

**Title:** New Jersey Prior Authorization Requirements for Select Drugs

**Policy #:** Rx.01.239

**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

**Intent:**

The intent of this policy is to communicate the medical necessity criteria for selected drugs with generic and/or therapeutic alternatives as provided under the member's prescription drug benefit.

**Description:**

The Prior Authorization Requirements for Select Drugs is designed to expedite and automate access to certain medications that require prior authorization (PA) by using information available in the member's prescription drug benefit claim history. If the prerequisite drug(s) is (are) in the claim history, the requested medication will be available at the point of sale without having their prescriber submit a PA request. If there is no history of the prerequisite drug(s) in a member's claim history, a PA request will be required per the standard process.

**Definitions:**

- A. Target: the medication to which the prior authorization is applied
- B. Prerequisite: the alternative medication(s) that must be used prior to approving the target medication

**Policy:**

A medication with an alternative or alternatives will be approved when ALL of the following are met:

- 1. FDA or compendia approved indication; and
- 2. Request is not for an excluded benefit (ie cosmetic); and
- 3. Inadequate response or inability to tolerate the alternative(s) listed

Target	Prerequisite(s)	Category
Mitigare®, Colcrys®, Gloperba®	colchicine tablets	Anti-gout
Febuxostat (Uloric®)	generic allopurinol	Anti-gout
Daytrana®, amphetamine ER 1.25mg/ml suspension [Adzenys® ER], Adzenys XR-ODT®, Dyanavel XR®, Mydayis®, Cotempla®, Evekeo ODT	2 generic ADHD stimulants (e.g. methylphenidate, amphetamines, etc)	ADHD
Concerta® Dexedrine® spansule Desoxyn® Metadate CD® Ritalin LA® Focalin XR® Adderall®, Kapvay®, Intuniv®, Strattera®	generic equivalent of requested brand	ADHD

Quillichew®, Quillivant®, Methylphenidate ER [Aptensio®], Jornay PM®, Adhansia XR®	Generic methylphenidate	ADHD
Atacand [HCT]®, Avapro [Avalide]®, Cozaar [Hyzaar]®, Diovan [HCT]®, Micardis [HCT]®, Exforge [HCT]®, Twynsta®, Benicar [HCT]®, Azor®, Tribenzor®, Edarbi®, Edarbyclor®, Tekturna [HCT]®, Byvalson®	3 generic angiotensin receptor blockers or combinations (e.g. losartan, olmesartan, valsartan, etc)	Angiotensin II receptor antagonists
Vasotec®, Zestril®, Prinivil®	3 generic angiotensin-converting enzyme (ACE) inhibitors (e.g. lisinopril, enalapril)	ACE-Inhibitors
Lamictal®	generic lamotrigine	anticonvulsants
Keppra®	generic levetiracetam	anticonvulsants
Briviact®	generic levetiracetam OR continuation of therapy with Briviact®	anticonvulsants
Wellbutrin XL®, Prozac®, Lexapro®, Zoloft®, Effexor XR®, Aplenzin®	3 generic antidepressants (e.g. citalopram, venlafaxine, bupropion, sertraline, etc)	Antidepressants
Topamax® [sprinkle]	topiramate	Anticonvulsants
Trokendi XR®, topiramate ER [Qudexy XR®]	generic topiramate IR OR continuation of therapy with Trokendi XR®, topiramate ER [Qudexy XR®]	Anticonvulsants
Xcopri®	Three generic anticonvulsants OR continuation of therapy with Xcopri®	Anticonvulsants
Trileptal®	Generic oxcarbazepine OR continuation of therapy with Trileptal®	Anticonvulsants
Fetzima®, Pristiq®, Khedezla®, Viibryd®	3 generic antidepressants (e.g. citalopram, venlafaxine, bupropion, sertraline, etc) OR continuous therapy with requested agent for a minimum of 2 weeks	Antidepressants
Trintellix®	2 generic antidepressants (e.g. citalopram, venlafaxine, bupropion, sertraline, etc) OR continuous therapy with requested agent for a minimum of 2 weeks	Antidepressants
Cymbalta®, Drizalma®	Duloxetine	Antidepressants
Fortamet®	2 generic metformin products	Anti-diabetics
Mytesi®	HIV therapy and ONE of the following: loperimide or diphenoxylate/ atropine	Antidiarrheal
Abilify®, Abilify Mycite®, Saphris®, Vraylar®, Fanapt®, Latuda®, Invega®, Rexulti®, Caplyta™, Secuado®	2 generic antipsychotic agents (e.g. aripirazole, paliperidone, quetiapine, risperidone, etc) OR continuation of therapy with requested medication	antipsychotics
Valtrex®	generic valacyclovir	Antivirals
Ativan®, Valium®, Xanax®, Klonopin®	3 generic benzodiazepines (e.g. lorazepam, diazepam, alprazolam, clonazepam, etc)	Benzodiazepine
Inderal LA®, Tenormin®, Tenoretic®, Kaspargo™	3 generic beta blockers (e.g. propranolol, atenolol, metoprolol, etc)	Beta blockers
Penicillamine [Cuprimine®], Trientine/Clovisque [Syprine®]	Depen®	Chelating agents
Adlyxin®	ONE of the following: Trulicity®, Byetta®, Bydureon®, Victoza®, Rybelsus® or Ozempic®	Anti-diabetics
Xultrophy	Soliqua	Anti-diabetics
Symlin®	Insulin within 180 days	Anti-diabetics
Non-preferred diabetic testing supplies (test strips and meters)	One Touch®	Anti-diabetics

Nesina®, Oseni®, Kazano®, Tradjenta®, Jentadueto®	Januvia® or Janumet® AND Onglyza® or Kombiglyze®	Anti-diabetics
Qtern®, Steglatro™, Steglujan™, Segluromet™, Invokana®, Invokamet® [XR]	One of the following: Jardiance®, Synjardy® [XR], Glyxambi® or Trijardy® XR AND One of the following: Farxiga® or Xigduo® XR	Anti-diabetics
Humulin®, Humalog® (insulin lispro), Apidra®, Admelog®, Lyumjev®, Fiasp®	One of the following: Novolin® or Novolog®	Anti-diabetics
Basaglar®, Levemir®, Tresiba®, Semglee®	One of the following: Lantus®, Toujeo®,	Anti-diabetics
Bravelle®, Follistim®	Gonal-F	Fertility
Lipitor®, Crestor®, Livalo®, Vytorin® Zypitamag®, Ezallor®	3 generic HMG CoA reductase inhibitors (e.g. simvastatin, atorvastatin, rosuvastatin, pravastatin, etc)	HMG Co A reductase inhibitors
Lovaza®	Omega-3-acid ethyl esters	Cholesterol lowering agents
Zetia®	generic ezetimibe	Cholesterol lowering agents
Vecamyl®	2 generic antihypertensives in different classes	Hypertension
Viberzi®	One antidiarrheal medication (e.g. loperamide) AND one antispasmodic (e.g. dicyclomine, etc)	IBS
Lubiprostone [Amitiza®]	Lactulose solution and ONE of the following: Linzess® or Symproic®	IBS
Trulance®, Zelnorm®	Both of the following: lactulose solution and Linzess®	IBS
Motegrity®	Linzess®	IBS
Extavia®, Rebif [Rebidose]®, Mavenclad®, Ponvory™	2 of the following: Avonex®, Betaseron®, glatiramer (Copaxone®, Glatopa®), Plegridy®, Vumerity®, Bafiertam®, dimethyl fumarate, Kesimpta® OR continuation of therapy with the requested agent	MS
Tecfidera®	Dimethyl fumarate AND One of the following: Vumerity® or Bafiertam®	MS
Conzip®, Qdolo®	2 generic tramadol products	Narcotic analgesic
Anaprox DS®, naproxen sodium ER [Naprelan CR®], Naprosyn®, EC-Naprosyn®, Celebrex®, Arthrotec®, Daypro®, Mobic®, Zipsor®, Fenoprofen, Fenortho™, Nalfon®, Qmiiz™ ODT, Relafen [DS®], indomethacin [Tivorbex®], Meloxicam [Vivlodex®], diclofenac [Zorvolex®], Ketoprofen 25mg caps, Cataflam®	3 generic prescription strength NSAIDS (e.g. ibuprofen, naproxen, diclofenac, celecoxib, meloxicam, etc)	NSAIDs
Butalbital/APAP 25/325mg tablet [Allzital®], Butalbital/APAP 50/300mg tabs/caps	Butalbital/APAP 50/325mg tabs	Non-Narcotic Analgesic
Vanatol S®, Vanatol LQ®	Butalbital/APAP/Caffeine 50/325mg/40mg tabs OR caps	Non-Narcotic Analgesic
Zioptan®, Vyzulta™, Rescula®, Xelpros®, Rocklatan®, Travatan Z®	ONE of the following generics: latanoprost, bimatoprost, travoprost AND Lumigan®	Ophthalmic prostaglandins
Bromsite®, Ilevro®, Nevanac®	Both of the following: Prolensa® and one generic (diclofenac, flurbiprofen, ketorolac)	Ophthalmic NSAIDs
Cequa™	Restasis®	Misc. ophthalmic agents

Toviaz®, Gemtesa®	Both of the following: Myrbetriq® AND 2 generic alternatives (e.g. solifenacin, oxybutynin, tolterodine, etc)	Overactive bladder agents
Vesicare®, Vesicare LS®	Generic Solifenacin	Overactive bladder
Xadago®	generic rasagiline and selegiline	Parkinson's disease
Rytary®	generic carbidopa/ levodopa	Parkinson's disease
Durlaza®	aspirin	Platelet inhibitors
ProAir Digihaler®, Proventil®, Albuterol [Ventolin®], Xopenex®	ProAir®	Pulmonary
Alvesco®, Asmanex®, Qvar®, Armonair®	Two of the following: Arnuity Ellipta®, Flovent Diskus/ HFA®, Pulmicort Flexhaler®	Pulmonary
Dulera®, AirDuo®	ONE of the following: Breo Ellipta®, Symbicort® or Advair® Diskus/HFA	Pulmonary
Utibron Neohaler®, Bevespi Aerosphere®, Duaklir®	ONE of the following: Anoro Ellipta®, Stiolto Respimat®	Pulmonary
Tudorza® Lanhala Magnair®, Seebri®, Yupelri™	ONE of the following: Spiriva® or Incruse® Ellipta	Pulmonary
Pancreaze®, Pertzye®, Viokace®	Both of the following: Creon® and Zenpep®	Pancreatic enzymes
Finacea®, Zilxi®	Soolantra®	Rosacea
Rhofade®	Mirvaso®	Rosacea
Noritrate®	Soolantra® or Mirvaso®	Rosacea
Skelaxin®, Soma®, Zanaflex®, Cyclobenzaprine ER [Amrix ER®], Lorzone®, Orphenadrine w/ aspirin & Caffeine [Norgesic Forte®, Orphengesic tab forte®]	2 generic skeletal muscle relaxants (e.g. metaxalone, carisoprodol, tizanidine, cyclobenzaprine, chlorzoxazone 500mg, etc)	Skeletal muscle relaxants
Ozobax™	Generic baclofen tablets	Skeletal muscle relaxants
Restoril®, Halcion®, Doral®	2 generic benzodiazepines indicated for sleep (e.g. temazepam, triazolam, quazepam, estazolam, etc)	Sleep agents
Ambien® 5mg [CR 6.25mg], Lunesta® 1mg, 2mg, Sonata®	2 generic sleep aids (e.g. zolpidem, eszopiclone, zaleplon, etc)	Sleep agents
Doxepin [Silenor®], Belsomra®, Dayvigo™	Two of the following: eszopiclone, zaleplon, zolpidem	Sleep agents
Nuvigil®, Provigil®	generic modafinil or armodafinil	Sleep agents
Acticlate®, Adoxa®, Avidoxy, Doryx DR®, Minocin®, Minolira™**, Monodox®, Solodyn**, Vibramycin®, doxycycline hyclate [Targadox®], Minocycline ER [Ximino®]**, Seysara™**, doxycycline hyclate 80mg ER	2 generic alternatives (e.g. doxycycline, minocycline, tetracycline)	Tetracyclines
Absorica [LD] ®	2 of the following: Amnesteem®, Claravis®, Myorisan®, Zenatane®	Acne agents
Duobrii®	Generic tazarotene cream and generic halobetasol	Topical steroid
Proctocort®	Hydrocortisone suppositories	Topical steroids
Eucrisa®	One of the following: one generic topical steroid (e.g. triamcinolone, clobetasol, halobetasol, etc) or one generic topical calcineurin inhibitor	Dermatological agents
Elidel®	One generic topical steroid (e.g. triamcinolone, clobetasol, halobetasol, etc) or generic tacrolimus	Dermatological agents
Protopic®	generic tacrolimus	Dermatological agents

Tazorac®, tazarotene [Fabior®]	Tazarotene	Topical acne agents
Differin®, Retin-A®, Retin-A micro®, Atralin®, Altreno™ Akliel®, Adapalene pad 0.1%, Arazlo®	2 generic topical vitamin A derivative products	Topical acne agents
Amzeeq®, Cleocin T®, Duac gel®, Evoclin foam®, Dapsone gel 7.5% [Aczone gel® 7.5%], Aczone gel® 5%, Azelex® cream®, Clindagel®,	2 generic, topical antibiotic or topical antibiotic combination products	Topical acne agents
Acanya®, Benzaclin gel®, Benzaclin pump®, Benzamycin gel®, Benzamycinpak gel®, Clindamycin/benzoyl peroxide 1% / 5%, Veltin gel®, Ziana®, Aktipak™	One of the following: Epiduo® Forte or Onexton®	Topical acne agents
Winlevi®	One generic topical vitamin A derivative product AND one generic topical antibiotic/topical antibiotic combination product	Topical acne agents
Noxafil	Generic posaconazole	Antiinfectives
ZMax®	generic azithromycin	Antiinfectives
Zyvox	generic linezolid	Antiinfectives
Lidoderm® patches, Ztlido™	generic lidocaine patch	Topical anesthetics
Loprox®, Extina®, Oxistat®, Ecoza®, Xolege®, luliconazole [Luzu®], mico-zn-petro [Vusion®], Ertaczo®, sulconazole [Exelderm®], oxiconazole	2 generic, prescription strength, topical antifungals (e.g. ketoconazole, , ciclopirox, etc)	Topical antifungal
Carac®	Fluorouracil 0.5% topical cream	Topical antineoplastics
Clobex®, Olux/ Olux E®, Ultravate®, Topicort®, Kenalog®, Luxiq®, clocortolone pivalate [Cloderm®], Desowen®, flurandrenolide [Cordran®, Nolix®], Dermasmoother®, Synalar®, Cutivate®, Locoid®, Locoid Lipocream®, Halog®, Desonate®, Verdeso®, Capex®, Pandel®, Sernivo®, halobetasol propionate [Lexette®], Bryhali®, diflorasone diacetate [Apexicon E®, Psorcon®], triamcinolone ointment 0.05% [Trianex®], Impeklo™	3 prescription strength, generic topical steroids	Topical steroid
Enstilar®, Taclonex®, calcipotriene/betamethasone [Taclonex®] suspension, Wyzora®	generic calcipotriene/ betamethasone or generic calcipotriene plus generic betamethasone	Topical steroid
Relistor®, Movantik®	BOTH of the following: Symproic® and lactulose solution	Opioid induced constipation
Rayaldee®	generic calcitriol	Vitamin D analog
Brand prenatal vitamins	3 generic prenatal vitamins (various)	Vitamins, prenatal
Levothyroxine [Tirosint®], Thyquidity™	Generic levothyroxine	Thyroid replacement
Actiq®, fentanyl citrate (Fentora®), Abstral®, Lazanda®, Subsys®	Generic oral transmucosal fentanyl citrate	TIRF
Zohydro®, Arymo® ER, Embeda®, Morphabond®	Two generic opioid analgesics or documentation of a history of or a potential for drug abuse for individual or a member of the individual's household	Opioid analgesics
Duragesic®, Dilaudid®, MS Contin®, Kadian®, AVINza®, Roxicodone®, Oxaydo®, Opana®, Percocet®, Norco®, Xodol®, Exalgo®, Vicoprofen®, Ibudone®, Demerol®, Actiq®, Dolophine®, Methadose®, Tylenol #3®, Tylenol #4®, Hycet®, Ultracet®, Ultram®, Fioricet® with codeine, Fiorinal® with codeine	Generic equivalent of requested brand	Opioid analgesics

Benzhydrocodone/Acetaminophen (Apadaz®)	Generic Hydrocodone/Acetaminophen and generic oxycodone/acetaminophen	Opioid analgesics
Primlev®, Prolate®, Oxycodone/Acetaminophen 2.5-300mg, 5-300mg, 10-300mg	Generic oxycodone/acetaminophen	Opioid analgesics
Oxycontin®, Oxycodone ER, Hysingla®	Xtampza® ER	Opioid analgesics
Reltone™	Generic ursodiol capsule	Gallstone agents
Xepi™, Altabax®	mupirocin	Impetigo agents
lactulose packet [Kristalose® packet]	lactulose solution	Laxative
Buphenyl tablet	generic sodium phenylbutyrate tablet	Metabolic modifiers
DDAVP	generic desmopressin acetate nasal spray	Posterior pituitary hormones
Pepcid	Two of the generics: famotidine, nizatidine, cimetidine, ranitidine	H2- Antagonists
Zileuton ER [Zyflo CR®]	Generic montelukast	Leukotriene modifiers
Zerviate™	Two of the following generics: azelastine, cromolyn sodium, epinastine)	Allergic conjunctivitis
Oxtellar XR®	generic oxcarbazepine OR continuation of therapy with Oxtellar XR®	Anticonvulsants
Aptiom®	Three generic anticonvulsants OR continuation of therapy with Aptiom®	Anticonvulsants
Tegretol®, Tegretol XR®, Carbatrol®	generic carbamazepine tablet OR continuation of therapy with Tegretol®, Tegretol XR®, Carbatrol®	Anticonvulsants
Neurontin®	Generic gabapentin	Anticonvulsants
Felbatol®	Generic felbamate	Anticonvulsants
Zonegran®	Generic zonisamide	Anticonvulsants
Glucagen®	ONE of the following: Glucagon®, Baqsimi®, Gvoke®	Glucagon agents
Nitisinone [Orfadin®]	Nityr	Hereditary Tyrosinemia
Cardizem CD®, Conjugpri®	3 generic calcium channel blockers (e.g. amlodipine, diltiazem, nifedipine, verapamil, etc)	Calcium channel blockers
Pamelor®	3 generic tricyclic antidepressants (e.g. nortriptyline, amitriptyline, imipramine, etc)	Tricyclic antidepressants
Asacol HD®	Generic mesalamine HD	Gastrointestinal agent
Lotronex®	Generic alosetron	Gastrointestinal agent
Gimoti™****	Generic oral metoclopramide	Gastrointestinal agent
Dexchlorpheniramine/Ryclora®	BOTH of the following generics (desloratadine, carbinoxamine/Ryvent®)	Antihistamines
Uceris®, Entocort EC®	Generic oral budesonide	Corticosteroid
Ortikos®	Generic budesonide cap 3mg DR (Entocort EC®)	Systemic glucocorticoid
Moviprep®, Plenvu®, Osmoprep®, Sutab®	Suprep® or Clenpiq®	Bowel prep agents
Golytely®, Nulytely®	PEG-3350 oral solution	Bowel prep agents
Cialis®, Viagra®, Levitra® (vardenafil), Staxyn® (vardenafil), Stendra®	One of the following: sildenafil or tadalafil AND no concurrent use of nitrate	Erectile dysfunction agent
Alkindi®	ONE generic oral corticosteroid (e.g. hydrocortisone, methylprednisolone)	Corticosteroid
Intrarosa®, Femring®, Vagifem®, Estrace cream®	Generic vaginal cream or vaginal tablet	Hormone replacement therapy
Ongentys®	Generic entacapone	Parkinson Disease

\*\*Solodyn®, Minolira™, Seysara™, Ximino® are approved for maximum of 84 days/180 days (authorization duration is 84 days)

\*\*\*Levemir® and Tresiba® do not require prior authorization for members under 6 years of age

\*\*\*\*Gimoti™ is approved for maximum of 56 days/180 days (authorization duration is 56 days)

**Black Box Warning as shown in the drug Prescribing Information:**

**Acetaminophen-containing agents**

Hepatotoxicity

Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing products.

**Acne Agents**

Absorica®, Absorica LD™

- a) Pregnancy Category X: Causes birth defects: Absorica™, Absorica LD™ must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking Absorica™, Absorica LD™ in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Absorica™, Absorica LD™ is available only through a restricted program called the iPLEDGE program. Prescribers, patients, pharmacies, and distributors must enroll in the program.

**ADHD stimulants**

Daytrana®, Concerta®, Metadate® CD, Ritalin LA®, Focalin®,

A. Drug dependence: should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use, since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up. CNS stimulants, including Focalin and Ritalin LA, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

Adzenys® ER, Adzenys XR-ODT™, Dyanavel® XR, Dexedrine®, Adderall®, QuilliChew ER™, Quilivant XR®, Aptensio XR™, Cotempla®

- a. Abuse and dependence: CNS stimulants, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. Administration of amphetamines for prolonged periods of time may lead to drug dependence and must be avoided. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy
- b. Particular attention should be paid to subjects obtaining amphetamines for non-therapeutic use or distribution to others, and the drugs should be prescribed sparingly.
- c. Misuse of amphetamine may cause sudden death and serious cardiovascular adverse events.

Desoxy®

- a. Methamphetamine has a high potential for abuse. It should thus be tried only in weight reduction programs for patients in whom alternative therapy has been ineffective. Administration of methamphetamine for prolonged periods of time in obesity may lead to drug dependence and must be avoided. Particular attention should be paid to the possibility of subjects obtaining methamphetamine for non-therapeutic use or distribution to others, and the drugs should be prescribed or dispensed sparingly. Misuse of methamphetamine may cause sudden death and serious cardiovascular adverse events.

## Strattera®

- a. Suicidal ideation in children and adolescents: increases the risk of suicidal ideation in short-term studies in children and adolescents with ADHD. Anyone considering the use in a child or adolescent must balance this risk with the clinical need. Co-morbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Strattera® is approved for ADHD in pediatric and adult patients. Strattera® is not approved for major depressive disorder. Pooled analyses of short-term (6 to 18 weeks) placebo-controlled trials in children and adolescents (a total of 12 trials involving over 2200 patients, including 11 trials in ADHD and 1 trial in enuresis) have revealed a greater risk of suicidal ideation early during treatment in those receiving Strattera® compared to placebo. The average risk of suicidal ideation in patients receiving Strattera® was 0.4% (5/1357 patients), compared to none in placebo-treated patients (851 patients). No suicides occurred in these trials.

## **Antihypertensives**

Atacand HCT®, Avapro®, Cozaar®, Diovan HCT®, Micardis® HCT, Teveten® HCT, Exforge HCT®, Twynsta®, Benicar HCT®, Azor®, Tribenzor®, Edarbi®, Edarbyclor®, Tekturna HCT®, Byvalson™

- a. Fetal toxicity: when pregnancy is detected, discontinue as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

## **Angiotensin-converting enzyme (ACE) inhibitors**

Vasotec®, Zestril®, Prinivil®, Altace®, Accupril®, Lotrel®

- A. When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function. In a published retrospective epidemiological study, infants whose mothers had taken an ACE inhibitor drug during the first trimester of pregnancy appeared to have an increased risk of major congenital malformations compared with infants whose mothers had not undergone first trimester exposure to ACE inhibitor drugs. The number of cases of birth defects is small and the findings of this study have not yet been repeated. When pregnancy is detected, discontinue ACEi as soon as possible.

## **Anticonvulsants**

Lamictal®

- a. Serious skin rashes: rashes requiring hospitalization and discontinuation of treatment. The incidence of these rashes, which have included Stevens-Johnson syndrome, is approximately 0.3% to 0.8% in pediatric patients (aged 2 to 17 years) and 0.08% to 0.3% in adults. One rash-related death was reported in a prospectively followed cohort of 1,983 pediatric patients (aged 2 to 16 years) with epilepsy taking Lamictal® as adjunctive therapy. In worldwide postmarketing experience, rare cases of toxic epidermal necrolysis and/or rash-related death have been reported in adult and pediatric patients, but their numbers are too few to permit a precise estimate of the rate. Other than age, there are as yet no factors identified that are known to predict the risk of occurrence or the severity of rash caused by Lamictal®. There are suggestions, yet to be proven, that the risk of rash may also be increased by (1) coadministration of Lamictal® with valproate (includes valproic acid and divalproex sodium), (2) exceeding the recommended initial dose of Lamictal® or (3) exceeding the recommended dose escalation for Lamictal®. However, cases have occurred in the absence of these factors. Nearly all cases of life-threatening rashes caused by Lamictal® have occurred within 2 to 8 weeks of treatment initiation. However, isolated cases have occurred after prolonged treatment (e.g., 6 months). Accordingly, duration of therapy cannot be relied upon as means to predict the potential risk heralded by the first appearance of a rash. Although benign rashes are also caused by Lamictal®, it is not possible to predict reliably which rashes will prove to be serious or life threatening. Accordingly, Lamictal® should ordinarily be discontinued at the first sign of rash, unless the rash is clearly not drug related. Discontinuation of treatment may not prevent a rash from becoming life threatening or permanently disabling or disfiguring.

Tegretol®, Tegretol XR®, Carbatrol®



- a. Serious and sometimes fatal dermatologic reactions, including Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), have been reported during treatment with Tegretol®, Tegretol XR®. These reactions are estimated to occur in 1 to 6 per 10,000 new users in countries with mainly Caucasian populations, but the risk in some Asian countries is estimated to be about 10 times higher. Studies in patients of Chinese ancestry have found a strong association between the risk of developing SJS/TEN and the presence of HLA-b\*1502, an inherited allelic variant of the HLA-b gene. HLA-b\*1502 is found almost exclusively in patients with ancestry across broad areas of Asia. Patients with ancestry in genetically at-risk populations should be screened for the presence of HLA-b\*1502 prior to initiating treatment with Tegretol®, Tegretol XR®. Patients testing positive for the allele should not be treated with Tegretol®, Tegretol XR® unless the benefit clearly outweighs the risk.
- b. Aplastic anemia and agranulocytosis have been reported in association with the use of Tegretol®, Tegretol XR®. Data from a population-based case control study demonstrate that the risk of developing these reactions is 5-8 times greater than in the general population. However, the overall risk of these reactions in the untreated general population is low, approximately six patients per one million population per year for agranulocytosis and two patients per one million population per year for aplastic anemia. Although reports of transient or persistent decreased platelet or white blood cell counts are not uncommon in association with the use of Tegretol®, Tegretol XR®, data are not available to estimate accurately their incidence or outcome. However, the vast majority of the cases of leukopenia have not progressed to the more serious conditions of aplastic anemia or agranulocytosis. Because of the very low incidence of agranulocytosis and aplastic anemia, the vast majority of minor hematologic changes observed in monitoring of patients on Tegretol®, Tegretol XR® are unlikely to signal the occurrence of either abnormality. Nonetheless, complete pretreatment hematological testing should be obtained as a baseline. If a patient in the course of treatment exhibits low or decreased white blood cell or platelet counts, the patient should be monitored closely. Discontinuation of the drug should be considered if any evidence of significant bone marrow depression develops.

#### Felbatol®

- a) The use of Felbatol® (felbamate) is associated with a marked increase in the incidence of aplastic anemia. Accordingly, Felbatol® should only be used in patients whose epilepsy is so severe that the risk of aplastic anemia is deemed acceptable in light of the benefits conferred by its use. Ordinarily, a patient should not be placed on and/or continued on Felbatol® without consideration of appropriate expert hematologic consultation. Among Felbatol® treated patients, aplastic anemia (pancytopenia in the presence of a bone marrow largely depleted of hematopoietic precursors) occurs at an incidence that may be more than a 100-fold greater than that seen in the untreated population (i.e., 2 to 5 per million persons per year). The risk of death in patients with aplastic anemia generally varies as a function of its severity and etiology; current estimates of the overall case fatality rate are in the range of 20 to 30%, but rates as high as 70% have been reported in the past. There are too few Felbatol® associated cases, and too little known about them to provide a reliable estimate of the syndrome's incidence or its case fatality rate or to identify the factors, if any, that might conceivably be used to predict who is at greater or lesser risk. In managing patients on Felbatol®, it should be borne in mind that the clinical manifestation of aplastic anemia may not be seen until after a patient has been on Felbatol® for several months (e.g., onset of aplastic anemia among Felbatol® exposed patients for whom data are available has ranged from 5 to 30 weeks). However, the injury to bone marrow stem cells that is held to be ultimately responsible for the anemia may occur weeks to months earlier. Accordingly, patients who are discontinued from Felbatol® remain at risk for developing anemia for a variable, and unknown, period afterwards. It is not known whether or not the risk of developing aplastic anemia changes with duration of exposure. Consequently, it is not safe to assume that a patient who has been on Felbatol® without signs of hematologic abnormality for long periods of time is without risk. It is not known whether or not the dose of Felbatol® affects the incidence of aplastic anemia.
- b) Evaluation of postmarketing experience suggests that acute liver failure is associated with the use of Felbatol®. The reported rate in the U.S. has been about 6 cases of liver failure leading to death or transplant per 75,000 patient years of use. This rate is an underestimate because of under reporting, and the true rate could be considerably greater than this. For example, if the reporting rate is 10%, the true rate would be one case per 1,250 patient years of use. Of the cases reported, about 67% resulted in death or liver transplantation, usually within 5 weeks of the onset of signs and symptoms of liver failure. The earliest onset of severe hepatic dysfunction followed subsequently by liver failure was 3 weeks after initiation of Felbatol®. Although some reports described dark urine and nonspecific prodromal symptoms (e.g., anorexia, malaise, and gastrointestinal symptoms), in other reports it was not clear if any prodromal symptoms preceded the onset of jaundice. It is not known whether or not the risk of developing hepatic failure changes with duration of exposure. It is not known whether or not the dosage of Felbatol® affects the incidence of hepatic failure. It is not known whether concomitant use of other antiepileptic drugs and/or other drugs affect the incidence of hepatic failure. Felbatol® should not be prescribed for anyone with a history of hepatic dysfunction. Treatment with Felbatol® should be initiated only in individuals without active liver disease and with normal baseline serum transaminases. It has not been proved that periodic serum transaminase testing will prevent serious injury but it is generally believed that early detection of drug induced hepatic injury along with immediate withdrawal of the suspect drug enhances the likelihood for recovery. There is no information available that documents how rapidly patients can progress from normal liver function to liver failure, but other drugs known to be hepatotoxins can cause liver failure rapidly (e.g., from normal enzymes to liver failure in 2-4 weeks). Accordingly, monitoring of serum transaminase levels (AST and ALT) is recommended at baseline and periodically thereafter. While the more frequent the monitoring the greater the chances of early detection, the precise schedule for monitoring is a matter of

clinical judgement. Felbatol® should be discontinued if either serum AST or serum ALT levels become increased  $\geq 2$  times the upper limit of normal, or if clinical signs and symptoms suggest liver failure. Patients who develop evidence of hepatocellular injury while on Felbatol® and are withdrawn from the drug for any reason should be presumed to be at increased risk for liver injury if Felbatol® is reintroduced. Accordingly, such patients should not be considered for re-treatment.

### **Antidepressants**

Wellbutrin XL®, Prozac®, Lexapro®, Zoloft®, Effexor XR®, Fetzima™, Trintellix®, Pristiq®, Khedezla™, Viibryd®, Aplenzin®, Cymbalta®, Pamelor™

- a. Suicidality and antidepressant drugs: antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction on risk with antidepressant use in patients aged 65 and older. In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.
- b. Prozac® is not approved for use in children less than 7 years of age.
- c. Lexapro® is not approved for use in pediatric patients less than 12 years of age.
- d. Fetzima™, Pristiq®, Effexor XR®, Khedezla™, & Pamelor™ are not approved for use in pediatric patients.
- e. Trintellix® & Viibryd® is not approved for use in pediatric patients.
- f. Aplenzin®: Serious neuropsychiatric reactions have occurred in patients taking bupropion for smoking cessation.

Drizalma®

#### **WARNING: SUICIDAL THOUGHTS AND BEHAVIORS**

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies.

Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors

### **Anti-diabetics**

Fortamet®, Kazano®, Jentaduetto®, Xigduo® XR, Segluromet™, Invokamet® XR

- a. Lactic acidosis: postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin-associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin-associated lactic acidosis was characterized by elevated blood lactate levels (greater than 5 mmol/L), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate/pyruvate ratio; and metformin plasma levels generally greater than 5 mcg/mL. Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), age 65 years old or greater, having a radiological study with contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided in the Full Prescribing Information. If metformin-associated lactic acidosis is suspected, immediately discontinue the drug and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.

Xultophy®

- a. Liraglutide and semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Xultophy® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined
- b. Xultophy® is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with the use and inform them of

the symptoms of thyroid tumors (e.g., mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound monitoring is of uncertain value for early detection of MTC in patients.

#### Symlin®

- a. Severe hypoglycemia: use with insulin increases the risk of severe hypoglycemia, particularly in patients with type 1 diabetes. When severe hypoglycemia occurs, it is seen within 3 hours following a Symlin® injection. Serious injuries may occur if severe hypoglycemia occurs while operating a motor vehicle, heavy machinery or while engaging in other high-risk activities. Appropriate patient selection, careful patient instruction, and insulin dose reduction are critical elements for reducing this risk.

#### Oseni®

- a. Congestive heart failure: thiazolidinediones, including pioglitazone, which is a component of Oseni®, cause or exacerbate congestive heart failure in some patients. After initiation of Oseni® and after dose increases, monitor patients carefully for signs and symptoms of heart failure (e.g., excessive, rapid weight gain, dyspnea and/or edema). If heart failure develops, it should be managed according to current standards of care and discontinuation or dose reduction of pioglitazone in Oseni® must be considered. It is not recommended in patients with symptomatic heart failure. Initiation of Oseni® in patients with established New York Heart Association (NYHA) Class III or IV heart failure is contraindicated.

#### Gimoti™

- a. Tardive dyskinesia: Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage. Discontinue Gimoti in patients who develop signs or symptoms of TD. Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the risk of developing TD with longer-term use.

### **Antipsychotics**

Abilify®, Abilify Mycite®, Saphris®, Vraylar™, Latuda®, Rexulti™, Secuado®

- a. Increased mortality in elderly patients with dementia-related psychosis: elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. They are not approved for the treatment of patients with dementia-related psychosis.
- b. Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction in risk with antidepressant use in patients aged 65 and older. In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.
- c. Latuda® is not approved for use in pediatric patients.
- d. The safety and efficacy of Rexulti™, Abilify Mycite®, Vraylar®, Rexulti®, & Secuado® have not been established in pediatric patients.
- e. Abilify® and Abilify Mycite® increases risk of suicidal thoughts and behavior in pediatric and young adult patients taking antidepressants. Closely monitor for worsening and emergence of suicidal thoughts and behaviors.

Fanapt®, Invega®, Caplyta™

- a. Increased mortality in elderly patients with dementia-related psychosis: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analysis of seventeen placebo-controlled trials (modal duration 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. They are not approved for the treatment of patients with Dementia-Related Psychosis.

## **Benzodiazepines**

Ativan®, Valium®, Xanax®, Klonopin®

- a. Risks from concomitant use with opioids: Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

## **Chelating agents**

Curprimine®

- a. Physicians planning to use penicillamine should thoroughly familiarize themselves with its toxicity, special dosage considerations, and therapeutic benefits. Penicillamine should never be used casually. Each patient should remain constantly under the close supervision of the physician. Patients should be warned to report promptly any symptoms suggesting toxicity.

## **Dermatological agents**

Elidel®, Protopic®

- A. Long-term Safety of Topical Calcineurin Inhibitors has not been established. Although a causal relationship has not been established, rare cases of malignancy (e.g., skin and lymphoma) have been reported in patients treated with topical calcineurin inhibitors. Therefore, continuous long-term use of topical calcineurin inhibitors in any age group should be avoided, and application limited to areas of involvement with atopic dermatitis. These agents are not indicated for use in children less than 2 years of age. Only 0.03% Protopic® ointment is indicated for use in children 2-15 years of age

## **Estrogen Products**

Estrace Cream®, Femring®, Vagifem®

Warning: endometrial cancer, cardiovascular disorders, breast cancer, and probable dementia

### Estrogen-Alone Therapy

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia
- The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT)
- The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

### Estrogen Plus Progestin Therapy

- Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia
- The WHI estrogen plus progestin substudy reported increased risks of stroke, DVT, pulmonary embolism (PE), and myocardial infarction (MI)
- The WHI estrogen plus progestin substudy reported an increased risk of invasive breast cancer
- The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

## **IBS**

Trulance™

- a. Risk of serious dehydration in pediatric patients: contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Avoid use in patients 6 years to less than 18 years of age. The safety and effectiveness of Trulance™ have not been established in patients less than 18 years of age.

#### Lotronex®

- a) Infrequent but serious gastrointestinal adverse reactions have been reported with the use of Lotronex®. These events, including ischemic colitis and serious complications of constipation, have resulted in hospitalization and, rarely, blood transfusion, surgery, and death. Lotronex® is indicated only for women with severe diarrhea predominant irritable bowel syndrome (IBS) who have not responded adequately to conventional therapy. Discontinue Lotronex® immediately in patients who develop constipation or symptoms of ischemic colitis. Do not resume Lotronex® in patients who develop ischemic colitis.

### **Bowel prep agents**

#### Osmoprep®

- A. Rare, serious reports of acute phosphate nephropathy in patients who received oral sodium phosphate products, including OsmoPrep, for colon cleansing prior to colonoscopy. Some cases have resulted in permanent impairment of renal function and some patients required long-term dialysis.
- B. Patients at increased risk include those with increased age, hypovolemia, increased bowel transit time (such as bowel obstruction), active colitis, or baseline kidney disease, and those using medicines that affect renal perfusion or function (such as diuretics, angiotensin-converting enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs], and possibly nonsteroidal antiinflammatory drugs [NSAIDs]).
- C. Advise patients of the importance of following the recommended split dosage regimen and the importance of adequate hydration before, during and after the use of OsmoPrep. Avoid additional sodium phosphate-based products.

### **MS agents**

#### Mavenclad®

- A. Malignancies: Mavenclad® may increase the risk of malignancy. Mavenclad® is contraindicated in patients with current malignancy; evaluate the benefits and risks on an individual basis for patients with prior or increased risk of malignancy. Follow standard cancer screening guidelines in patients treated with Mavenclad®.
- B. Risk of Teratogenicity: Mavenclad® is contraindicated for use in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the risk of fetal harm. Malformations and embryolethality occurred in animals. Exclude pregnancy before the start of treatment with Mavenclad® in females of reproductive potential. Advise females and males of reproductive potential to use effective contraception during Mavenclad® dosing and for 6 months after the last dose in each treatment course. Stop Mavenclad® if the patient becomes pregnant.

### **Narcotic analgesics**

#### ConZip®, Ultram®, Ultracet®, Qdolo™

- a. Addiction abuse and misuse: exposes patients and others to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing and monitor all patients regularly for the development of these behaviors and conditions.
- b. Life-threatening respiratory depression: serious, life-threatening, or fatal respiratory depression may occur with use. Monitor for respiratory for respiratory depression, especially during initiation or following a dose increase. Instruct patients to swallow ER tablets intact, and not to cut, break, chew, crush or dissolve the tablets to avoid exposure to potentially fatal dose.
- c. Accidental ingestion: accidental exposure, especially by children, can result in fatal overdose.
- d. Neonatal opioid withdrawal syndrome: prolonged use during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that the appropriate treatment will be available.

- e. Interactions with drugs affecting cytochrome P450 isoenzymes: the effects of concomitant use or discontinuation of cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with tramadol are complex and requires careful consideration of the effects on the parent drug and the active metabolite.
- f. Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

## **NSAIDs**

Anaprox® DS, Naprelan® CR, Naprosyn®, EC-Naprosyn®, Celebrex®, Arthrotec®, Daypro®, Mobic®, Volatren® XR, Zipsor®, Tivorbex™, Vivlodex®, Zorvolex®, Cataflam®

- a. Cardiovascular risk: NSAIDs cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. These agents are contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
- b. Gastrointestinal risk: NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer and/or GI bleeding are at greater risk for serious gastrointestinal events.
- c. For diclofenac and misoprostol (Arthrotec®), the administration to women who are pregnant can cause abortion, premature birth, or birth defects. Uterine rupture has been reported when misoprostol was administered to pregnant women to induce labor or to induce abortion beyond the eighth week of pregnancy. Diclofenac/misoprostol should not be taken by pregnant women.

## **Opioid Analgesics**

**1. Life-Threatening Respiratory depression: TIRFs (Actiq®, Abstral®, Fentora®, Subsys®), Lazanda®, Duragesic®, Fiorinal®, Hydromorphone (Dilaudid, Exalgo®), Hysingla™ ER, Morphine Sulfate: Arymo™ ER, Avinza®, Kadian®, and MS Contin®, Morphabond ER®, Opana ER®, Oxycodone (Oxycontin®, Oxaydo®), Zohydro ER™ (hydrocodone ER), Primlev®, Prolate™, Nalocet®**

Fatal respiratory depression has occurred in patients treated with the above listed opioid products, including following use in opioid-intolerant patients and improper dosing. Be sure to monitor for sign and symptoms of respiratory depression, especially during initiation of the drugs. The substitution of fentanyl sublingual/buccal for any other fentanyl product may result in fatal overdose. Because of the risk of respiratory depression, fentanyl products are contraindicated for use as an as-needed analgesic, or in the management of acute or postoperative pain, including headache/migraine and in opioid-intolerant patients. In addition, the concomitant use of fentanyl sublingual with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations and may cause potentially fatal respiratory depression.

For hydromorphone and ER products like morphine ER, oxycodone ER, tapentadol ER, and oxymorphone ER products, instruct patients to swallow a whole tablet. Crushing, chewing, snorting, or dissolving tablets can cause rapid release and absorption that could lead to fatal overdose and even death. Note: Avinza® capsule contents may be sprinkled on applesauce and swallowed without chewing<sup>19</sup>. Hydromorphone is a potent Schedule II controlled opioid agonist. Schedule II opioid agonists have the highest potential for abuse and risk of producing respiratory depression. Alcohol, other opioids, and CNS depressants (sedative-hypnotics) potentiate the respiratory depressant effects of hydromorphone, increasing the risk of respiratory depression that might result in death.

**2. Medication errors: TIRFs (Actiq®, Abstral®, Fentora®, Subsys®), Lazanda®**

Substantial differences exist in the pharmacokinetic profile of fentanyl sublingual/buccal compared with other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in fatal overdose. When prescribing, do not convert patients on a mcg-per-mcg basis from any other fentanyl products to fentanyl sublingual/buccal. When dispensing, do not substitute a fentanyl sublingual/buccal prescription for other fentanyl products.

**3. Addiction and Abuse potential: TIRFs (Actiq®, Abstral®, Fentora®, Subsys®), Lazanda®, Duragesic®, Hydromorphone (Dilaudid, Exalgo®), Fiorinal®, Hysingla™ ER, Morphine Sulfate: Arymo™ ER, Avinza®, Kadian®, and MS Contin®, Morphabond ER®, Opana ER®, Oxycodone (Oxycontin®, Oxaydo®), Zohydro ER™ (hydrocodone ER), Primlev®, Prolate™, Nalocet®**

All opioid analgesics regardless of formulation are classified as Schedule II controlled substance, with high abuse liability. They expose patients and drug users to the risk of opioid addiction, abuse, and misuse, which can lead to overdose and death. Diversion,

addiction, and abuse potential should be considered when prescribing or dispensing opioid analgesics. Providers must monitor all patients regularly for the development of these behaviors or conditions. Due to the risk for misuse, abuse, addiction, and overdose, some products such as fentanyl sublingual/buccal is available only through a restricted program required by the Food and Drug Administration, called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, outpatients, health care providers who prescribe to outpatients, pharmacies, and distributors must enroll in the program. Further information is available at <http://www.TIRFREMSaccess.com> or by calling 1-866-822-1483.

**4. Cytochrome P450 3A4 interaction: TIRFs (Actiq<sup>®</sup>, Abstral<sup>®</sup>, Fentora<sup>®</sup>, Subsys<sup>®</sup>), Fiorinal<sup>®</sup>, Lazanda<sup>®</sup>, Duragesic<sup>®</sup>, Oxycodone (Oxycontin<sup>®</sup>, Oxaydo<sup>®</sup>), Zohydro ER<sup>™</sup> (hydrocodone ER), Primlev<sup>®</sup>, Prolate<sup>™</sup>, Hysingla<sup>™</sup>, Nalocet<sup>®</sup>**

The concomitant use of fentanyl, oxycodone ER and hydrocodone ER with all cytochrome P450 3A4 (CYP3A4) inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodone plasma concentration. Monitor patients receiving oxycodone ER and any CYP3A4 inhibitor or inducer.

**5. Accidental exposure: Duragesic<sup>®</sup>, Hydromorphone (Dilaudid, Exalgo<sup>®</sup>), Morphine Sulfate: Arymo<sup>™</sup> ER, Avinza<sup>®</sup>, Kadian<sup>®</sup>, MS Contin<sup>®</sup>, Morphabond ER<sup>®</sup>, Opana ER<sup>®</sup>, Oxycodone (Oxycontin<sup>®</sup>, Oxaydo<sup>®</sup>), Zohydro ER<sup>™</sup>, Primlev<sup>®</sup>, Nalocet<sup>®</sup>**  
Deaths due to a fatal overdose of the above listed opioid analgesics have occurred when children and adults were accidentally exposed to the drugs. Strict adherence to the recommended handling and disposal instructions is of the utmost importance to prevent accidental exposure. Accidental ingestion of even 1 dose, especially in children, can result in a fatal overdose and death.

**6. Neonatal opioid withdrawal syndrome:**

Prolonged use of opioid analgesics especially Duragesic<sup>®</sup>, Hydromorphone (Exalgo<sup>®</sup>), Fiorinal<sup>®</sup>, Hysingla<sup>™</sup> ER, Morphine Sulfate: Arymo<sup>™</sup> ER, Avinza<sup>®</sup>, Kadian<sup>®</sup>, and MS Contin<sup>®</sup>, Morphabond ER<sup>®</sup>, Opana ER<sup>®</sup> (tapentadol ER, and oxymorphone ER), Zohydro ER<sup>™</sup>, Oxycodone (Oxycontin<sup>®</sup>, Oxaydo<sup>®</sup>), Primlev<sup>®</sup>, Prolate<sup>™</sup>, Nalocet<sup>®</sup> can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

**7. Exposure to heat: Duragesic<sup>®</sup> (31)**

Exposure of the fentanyl application site and surrounding area to direct external heat sources, such as heating pads or electric blankets, heat or tanning lamps, sunbathing, hot baths, saunas, hot tubs, and heated water beds may increase fentanyl absorption and has resulted in fatal overdose of fentanyl and death. Patients wearing fentanyl systems who develop fever or increased core body temperature due to strenuous exertion are also at risk for increased fentanyl exposure and may require an adjustment in the dose of fentanyl to avoid overdose and death. Warn patients to avoid exposing the application site and surrounding area to direct external heat sources.

**8. Interaction with alcohol: Morphine Sulfate: Avinza<sup>®</sup>, Kadian<sup>®</sup>, and MS Contin<sup>®</sup>, Opana ER<sup>®</sup>, Zohydro ER<sup>™</sup>, Oxycodone (Oxycontin<sup>®</sup>, Oxaydo<sup>®</sup>)**

When using with alcohol, all opioid analgesic products have the potential to cause excessive sedation and may increase blood concentration of certain opioids like tapentadol, oxymorphone, and morphine. This could lead to fatal overdose and death. Instruct patients to avoid alcoholic beverages or use prescription or nonprescription products that contain alcohol while taking opioid analgesics.

**9. Information about oral morphine and oxycodone solution: Morphine Sulfate: Avinza<sup>®</sup>, Kadian<sup>®</sup>, and MS Contin<sup>®</sup>, Oxycodone (Oxycontin<sup>®</sup>, Oxaydo<sup>®</sup>)**

Morphine oral solution is available in 10 mg per 5 mL, 20 mg per 5 mL, and 100 mg per 5 mL (20 mg/mL) concentrations. The 100 mg per 5 mL (20 mg/mL) concentration is indicated for use in opioid-tolerant patients only. Take care when prescribing and administering morphine oral solution to avoid dosing errors due to confusion between different concentrations and between milligrams and milliliters, which could result in accidental overdose and death. Take care to ensure the proper dose is communicated and dispensed. Keep morphine oral solution out of the reach of children. In case of accidental ingestion, seek emergency medical help immediately.

Oxycodone concentrated oral solution is available as a 20 mg/mL concentration and is indicated for use in opioid-tolerant patients only. Take care when prescribing and administering oxycodone concentrated oral solution to avoid dosing errors due to confusion between milligram and milliliter, and other oxycodone solutions with different concentrations, which could result in accidental

overdose and death. Take care to ensure the proper dose is communicated and dispensed. Keep oxycodone out of the reach of children. In case of accidental ingestion, seek emergency medical help immediately.

#### **10. Risks from Concomitant Use with Benzodiazepines or other CNS Depressants: Arymo™ ER, Hysingla™ ER, Morphabond ER®, Primlev®, Prolate™, Nalocet®**

Concomitant use of opioid with benzodiazepines or other CNS depressants may result in profound sedation, respiratory depressions, coma, and death. Addiction, abuse and misuse: life-threatening respiratory depression, accidental ingestion; neonatal opioid withdrawal; and risks from concomitant use with benzodiazepines or other CNS depressants.

1. Morphabond ER: Risk evaluation and mitigation strategy (REMS).
2. Primlev®: Hepatotoxicity, cytochrome P450 3A4 interaction
3. Prolate™: Hepatotoxicity, cytochrome P450 3A4 interaction

#### **Sleep agents**

Restoril™, Halcion®, Doral®,

Risk from concomitant use with opioids: Concomitant use of benzodiazepines and opioids: may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and duration to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

Zolpidem tartrate (Ambien® and Ambien CR®), zolpidem (Intermezzo®, Zolpimist®), zolpidem tartrate sublingual tablets (Eduar®), eszopiclone 3mg (Lunesta®)

Complex sleep behaviors including sleepwalking, sleep driving, and engaging in other activities while not fully awake have been reported following use of zolpidem tartrate and eszopiclone. Some of these events have resulted in serious injuries, including death. Discontinue immediately if a patient experiences a complex sleep behavior.

#### **Thyroid replacement agents**

Thyquidity™: Thyroid hormones, including THYQUIDITY, should not be used for the treatment of obesity or for weight loss. Doses beyond the range of daily hormonal requirements may produce serious or even life-threatening manifestations of toxicity.

#### **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

#### **BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

#### **References:**

Abilify® (aripiprazole) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; June 2020. [https://www.otsuka-us.com/media/static/Abilify-PI.pdf?\\_ga=2.198787951.192181128.1550591449-504866814.1550591449&\\_gac=1.241372598.1550591449.EAlalQobChMlxOPFopPI4AIVha\\_ICh3ZMA0vEAAAYASAAEgLiv\\_D\\_BwE](https://www.otsuka-us.com/media/static/Abilify-PI.pdf?_ga=2.198787951.192181128.1550591449-504866814.1550591449&_gac=1.241372598.1550591449.EAlalQobChMlxOPFopPI4AIVha_ICh3ZMA0vEAAAYASAAEgLiv_D_BwE) Accessed July 23, 2021.

Abilify Mycite® (aripiprazole) [prescribing information]. Rockville, MD: Otsuka America Pharmaceuticals, Inc. December 2020. Available at: [https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?\\_ga=2.72681619.1482915875.1558442487-890748463.1558442487](https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?_ga=2.72681619.1482915875.1558442487-890748463.1558442487). Accessed July 23, 2021.



Absorica® (isotretinoin) [package insert]. Jacksonville, FL: Ranbaxy Laboratories Inc.; October 2019. [https://www.absorica.com/pdf/Absorica\\_Prescribing\\_Information.pdf](https://www.absorica.com/pdf/Absorica_Prescribing_Information.pdf) Accessed July 23, 2021.

Absorica LD™ (isotretinoin) [prescribing information]. United Kingdom: M W Encap Ltd; October 2019. Available from: [https://www.absorica.com/pdf/Absorica\\_Prescribing\\_Information.pdf](https://www.absorica.com/pdf/Absorica_Prescribing_Information.pdf). Accessed July 23, 2021.

Abstral® (fentanyl tablet) [package insert]. Bridgewater, NJ: Norvartis Consumer Health, Inc. May 2017 [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/022510s013lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022510s013lbl.pdf). Accessed July 23, 2021.

Acanya® (clindamycin phosphate and benzoyl peroxide) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; October 2016. Accessed July 23, 2021. Aklief® (trifarotene) [package insert] Fort Worth, Texas. Galderma Laboratories, L.P. October 2019. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=62d910db-85a6-4696-b69b-4bd2f3080cfc&type=display>. Accessed on July 23, 2021.

Actiq® (fentanyl citrate) [prescribing information]. North Wales, PA: Teva Pharmaceuticals Inc. October 2019. <http://www.actiq.com/pdf/ActiqDigitalPIandMedGuide.pdf> Accessed July 23, 2021.

Accupril® (quinapril) [prescribing information]. New York, NY: Pfizer Inc.; November 2019. Available from: <http://labeling.pfizer.com/ShowLabeling.aspx?id=518>. Accessed July 23, 2021.

Advair Diskus® (fluticasone propionate and salmeterol) [prescribing information]. Research Triangle Park, NC. GlaxoSmithKline; January 2019. Available from: [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Advair\\_Diskus/pdf/ADV AIR-DISKUS-PI-PIL-IFU.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Advair_Diskus/pdf/ADV AIR-DISKUS-PI-PIL-IFU.PDF). Accessed July 23, 2021.

Advair® HFA (fluticasone propionate and salmeterol) [prescribing information]. Research Triangle Park, NC. GlaxoSmithKline; March 2020. Available from: [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Advair\\_HFA/pdf/ADV AIR-HFA-PI-PIL-IFU.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Advair_HFA/pdf/ADV AIR-HFA-PI-PIL-IFU.PDF). Accessed July 23, 2021.

Acticlate® (doxycycline hyclate) [prescribing information]. West Chester, PA: Aqua Pharmaceuticals; October 2017. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/208253s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208253s000lbl.pdf) Accessed July 23, 2021.

Aczone® (dapson) [prescribing information]. Parsippany, NJ: Allergan, Inc; September 2019. <https://www.almirall.us/pdf/ACZONE-75-USPI-v1-20180518.pdf> Accessed July 23, 2021.

Admelog® (insulin lispro) [prescribing information]. Sanofi-Aventis U.S. LLC. November 2019. <http://products.sanofi.us/admelog/admelog.pdf>. Accessed July 23, 2021.

Adlyxin™ (lixisenatide) [prescribing information]. Paris, France: Sanofi-Aventis U.S. LLC; January 2019 <http://products.sanofi.us/adlyxin/adlyxin.pdf> Accessed July 23, 2021.

Adoxa® (doxycycline) [prescribing information]. Princeton, NJ: PharmaDerm a division of Fougera Pharmaceuticals Inc.; May 2013. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0cecc43f-cc40-4c48-9e43-ae8d77af4e49> Accessed July 23, 2021.

Adzenys ER® (amphetamine) [prescribing information]. Grand Prairie, TX: Neos Therapeutics; December 2017. Accessed July 23, 2021.

Adzenys XR-ODT™ (amphetamine) [prescribing information]. Grand Prairie, TX: Neos Therapeutics; December 2017. [http://www.neostxcontent.com/Labeling/Adzenys/Adzenys\\_PI.pdf](http://www.neostxcontent.com/Labeling/Adzenys/Adzenys_PI.pdf) Accessed July 23, 2021.

AirDuo™ Respiclick® (fluticasone propionate and salmeterol) [prescribing information]. Miami, FL: Teva Respiratory, LLC; February 2020. <http://hcp.myairduo.com/Assets/Pdf/PI.pdf>. Accessed July 23, 2021.

Aktipak™ (erythromycin and benzoyl peroxide gel) [prescribing information]. Wayne, PA: Cutanea Life Sciences, Inc.; January 2017. Available at: [http://www.aktipak.com/wp-content/themes/Aktipak/img/pdf/CUTA\\_11042\\_AKT-WEBSITE\\_DV1\\_021717\\_Desktop\\_FULL\\_PI.pdf](http://www.aktipak.com/wp-content/themes/Aktipak/img/pdf/CUTA_11042_AKT-WEBSITE_DV1_021717_Desktop_FULL_PI.pdf). Accessed July 23, 2021.

Altanax® (retapamulin) [prescribing information]. Exton, PA: Aqua Pharmaceuticals. December 2012. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/022055s002lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022055s002lbl.pdf). Accessed July 23, 2021.

Altace® (ramipril) [prescribing information]. New York, NY: Pfizer Inc.; June 2017. Available from: <http://labeling.pfizer.com/ShowLabeling.aspx?id=716>. Accessed July 23, 2021.

Altreno™ (tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2020. Available at: <https://www.bauschhealth.com/Portals/25/Pdf/PI/altreno-pi.pdf>. Accessed July 23, 2021.

Alvesco® (ciclesonide) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; October 2020. [https://www.alvesco.us/\\_resources/100296-Alvesco-PI-Nov%202017.pdf](https://www.alvesco.us/_resources/100296-Alvesco-PI-Nov%202017.pdf). Accessed July 23, 2021.

Ambien® (zolpidem tartrate) [prescribing information]. Paris, France: Sanofi-Aventis U.S. LLC; August 2019. <http://products.sanofi.us/ambien/ambien.pdf>. Accessed July 23, 2021.

Ambien® CR (zolpidem tartrate) [prescribing information]. Paris, France: Sanofi-Aventis U.S. LLC; August 2019. <http://products.sanofi.us/ambien/ambien.pdf>. Accessed July 23, 2021.

Amitiza® (lubiprostone) [prescribing information]. Lake County, IL: Takeda Pharmaceuticals America, Inc.; November 2020. <https://general.takedapharm.com/amitizapi>. Accessed July 23, 2021.

Amrix® (cyclobenzaprine hydrochloride) [prescribing information]. Malvern, PA: Cephalon, Inc.; May 2020. <http://www.amrix.com/Content/Pdf/prescribing-information.pdf>. Accessed July 23, 2021.

Amzeeq™ (minocycline) [prescribing information]. Mohlin, Switzerland: ASM Aerosol-Service AG; January 2021. Available from: <https://www.amzeeq.com/sites/default/files/documents/foamix-amzeeq-prescribing-information.pdf>. Accessed July 23, 2021.

Anaprox® DS (naproxen) [prescribing information]. Phoenixville, PA: Genentech, Inc.; March 2017. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/017581s113.018164s063.020067s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017581s113.018164s063.020067s020lbl.pdf). Accessed July 23, 2021.

Apexicon E® (diflorasone diacetate) [prescribing information]. Melville, NY: Fougeral Pharmaceuticals Inc. October 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=af4c413b-c228-48f0-9ad0-6434d1f921b9>. Accessed July 23, 2021.

Apidra® (insulin glulisine) [prescribing information]. Paris, France: Sanofi-Aventis U.S. LLC; November 2019. <http://products.sanofi.us/apidra/apidra.html>. Accessed July 23, 2021.

Aplenzin® (bupropion hydrobromide) [package insert]. Bridgewater, NJ: Sanofi-Aventis US LLC; June 2020. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/022108s007lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022108s007lbl.pdf). Accessed July 23, 2021.

Aptensio XR™ (methylphenidate) [prescribing information]. Coventry, RI: Rhodes Pharmaceuticals; June 2019. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5adedc01-ebf0-11e3-ac10-0800200c9a66>. Accessed July 23, 2021.

Aptiom® (eslicarbazepine acetate) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc. March 2019. Available from: <https://www.aptiom.com/Aptiom-Prescribing-Information.pdf>. Accessed July 23, 2021.

Arazlo™ (tazaotene) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; December 2019. Available from: <https://www.bauschhealth.com/portals/25/pdf/pi/arazlo-pi.pdf>. Accessed July 23, 2021.

Armonair® (fluticasone propionate) [package insert]. Frazer, PA: Teva Respiratory, LLC; March 2018. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/208798s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208798s000lbl.pdf). Accessed July 23, 2021.

Arthrotec® (diclofenac sodium and misoprostol) [prescribing information]. Skokie, IL: G.D. Searle LLC Division of Pfizer Inc; July 2020. <http://labeling.pfizer.com/showlabeling.aspx?id=526>. Accessed July 23, 2021.

Arymo ER® (morphine sulfate) [package insert]. Wayne, PA. Egalet US Inc. October 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=e60552c9-06ce-4790-95e7-aadd4df12b2a&type=display>. Accessed July 23, 2021.

Asmanex® HFA (mometasone furoate) [prescribing information]. Whitehouse, NJ: Merck & Co., Inc. August 2020. Available from: [https://www.merck.com/product/usa/pi\\_circulars/a/asmanex\\_hfa/asmanex\\_hfa\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/a/asmanex_hfa/asmanex_hfa_pi.pdf). Accessed July 23, 2021.

Asmanex Twisthaler® (mometasone furoate inhalation powder) [prescribing information]. Whitehouse, NJ: Merck & Co., Inc. December 2019. Available from: [https://www.merck.com/product/usa/pi\\_circulars/a/asmanex/asmanex\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/a/asmanex/asmanex_pi.pdf). Accessed July 23, 2021.

Atacand HCT® (candesartan cilexetil and hydrochlorothiazide) [prescribing information]. Gaithersburg, MD: AstraZeneca Pharmaceuticals LP; February 2016. Accessed July 23, 2021.

Ativan® (lorazepam) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; January 2019. Accessed July 23, 2021.

Atralin® (tretinoin) [prescribing information]. Fort Worth, TX: Coria Laboratories; 2014. Accessed July 23, 2021.

Avalide® (irbesartan and hydrochlorothiazide) [prescribing information]. Paris, France: Sanofi-Aventis U.S. LLC; July 2018. Accessed July 23, 2021.

Avapro® (irbesartan) [prescribing information]. Paris, France: Sanofi-Aventis U.S. LLC; August 2019. <http://products.sanofi.us/Avapro/Avapro.pdf> Accessed July 23, 2021.

[Avinza \(morphine\) Medication Guide](#). Available at <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM311346.pdf>. Accessed July 23, 2021.

Azelex® (azelaic acid) [prescribing information]. Parsippany, NJ: Allergan, Inc; 2017. Accessed July 23, 2021.

Azor® (amlodipine besylate and olmesartan medoxomil) [prescribing information]. Parsippany, NJ: Daiichi Sankyo, Inc.; October 2020. <https://dsi.com/prescribing-information-portlet/getPICContent?productName=Azor&inline=true> Accessed July 23, 2021.

Basaglar® (insulin glargine) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; November 2019. <http://pi.lilly.com/us/basaglar-uspi.pdf> Accessed July 23, 2021.

Belsomra® (suvorexant) [prescribing information]. Kenilworth, NJ: Merck Sharp & Dohme Corp; February 2021. [https://www.merck.com/product/usa/pi\\_circulars/b/belsomra/belsomra\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/b/belsomra/belsomra_pi.pdf) Accessed July 23, 2021.

Benicar HCT® (olmesartan medoxomil-hydrochlorothiazide) [prescribing information]. Parsippany, NJ: Daiichi Sankyo, Inc.; May 2020. <https://dsi.com/prescribing-information-portlet/getDocument?product=BNHCT&inline=true> Accessed July 23, 2021.

Benzaclin® (clindamycin phosphate and benzoyl peroxide) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2017. Accessed July 23, 2021.

Benzamycin® (erythromycin and benzoyl peroxide) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2016. Accessed July 23, 2021.

Bevespi Aerosphere™ (glycopyrrolate and formoterol fumarate) [prescribing information]. Gaithersburg, MD: AstraZeneca Pharmaceuticals LP; November 2020. <https://www.azpicentral.com/bevespi/bevespi.pdf#page=1> Accessed July 23, 2021.

Bravelle® (urofollitropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; May 2018. <http://www.ferringusa.com/wp-content/uploads/2016/02/BravellePI-2.2014.pdf> Accessed July 23, 2021.

Briviact® (brivaracetam) [prescribing information]. Smyrna, GA: UCB Inc.; May 2018. <https://www.briviact.com/briviact-PI.pdf> Accessed July 23, 2021.

Bromsite® (bromfenac ophthalmic solution) [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc. April 2016. Available at: <https://www.bromsite.com/pdf/BromSitePI.pdf>. Accessed July 23, 2021.

Bryhali® (halobetasol propionate) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. June 2020. Available at: <https://www.bauschhealth.com/Portals/25/Pdf/PI/Bryhali-PI.pdf>. Accessed July 23, 2021.

Byvalson™ (nebivolol hydrochloride and valsartan) [prescribing information]. Parsippany, NJ: Allergan, Inc; June 2016. [https://www.allergan.com/assets/pdf/byvalson\\_pi](https://www.allergan.com/assets/pdf/byvalson_pi) Accessed July 23, 2021.

Capex® (fluocinolone) [prescribing information]. Fort Worth, TX: Galderma Laboratories, L.P.; 2015. Accessed July 23, 2021.

Caplyta™ (lumateperone) [prescribing information]. New York, NY: Intra-Cellular Therapies, Inc. December 2019. Available from: [https://www.intracellulartherapies.com/docs/caplyta\\_pi.pdf](https://www.intracellulartherapies.com/docs/caplyta_pi.pdf). Accessed July 23, 2021.

Carac® (fluorouracil) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; May 2017. <https://www.bauschhealth.com/Portals/25/Pdf/PI/Carac-PI.pdf> Accessed July 23, 2021.

Carbatrol® (carbamazepine) [prescribing information]. Wayne, PA: Shire US Inc. March 2013. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/020712s032s035lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020712s032s035lbl.pdf). Accessed July 23, 2021.

Cataflam® (diclofenac potassium immediate-release tablets) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2016. Available from: <https://www.novartis.us/sites/www.novartis.us/files/Cataflam.pdf>. Accessed July 23, 2021.

Celebrex® (celecoxib) [prescribing information]. Skokie, IL: G.D. Searle LLC Division of Pfizer Inc; May 2019. <http://labeling.pfizer.com/ShowLabeling.aspx?id=793> Accessed July 23, 2021.

Cequa™ (cyclosporin ophthalmic solution) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc. September 2019. Available at: <https://cequapro.com/pdf/CequaPI.pdf>. Accessed July 23, 2021.

Cleocin® (clindamycin phosphate) [prescribing information]. Kalamazoo, MI: Pharmacia and Upjohn Company LLC; 2017. Accessed July 23, 2021.

Clindagel® (clindamycin) [prescribing information]. Cumberland, RI: Onset Dermatologics LLC; November 2017. <https://www.bauschhealth.com/Portals/25/Pdf/PI/Clindagel-PI.pdf> Accessed July 23, 2021.

Clindamycin Phosphate and Benzoyl Peroxide Gel 1%/5% [prescribing information]. Sugar Land, TX. 2017. Accessed July 23, 2021.

Clobex® (clobetasol propionate) [prescribing information]. Fort Worth, TX: Galderma Laboratories, L.P.; 2014. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/021644s002lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021644s002lbl.pdf) Accessed July 23, 2021.

Cloderm® (clocortolone pivalate) [prescribing information]. Bridgewater, NJ: Promius Pharma, LLC; June 2017. <http://www.clodermcream.com/wp-content/uploads/2018/09/ClodermCreamPI.pdf> Accessed July 23, 2021.

Clovique® (trientine hydrochloride) [prescribing information]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; December 2018. Available from: [https://www.clovique.com/wp-content/uploads/2018/12/package\\_insert.pdf](https://www.clovique.com/wp-content/uploads/2018/12/package_insert.pdf). Accessed July 23, 2021.

Colcrys® (colchicine) [prescribing information]. Philadelphia, PA. AR Scientific Inc.; May 2020. <https://general.takedapharm.com/COLCRYSPI> Accessed July 23, 2021.

Conjupri™ (levamlodipine) [prescribing information]. Hot Springs, AR: Burke Therapeutics, LLC; August 2020. Available from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d1c7a0f2-9b6c-44a2-9e8c-70c3ce8a2aa8>. Accessed July 23, 2021.

Concerta® (methylphenidate) [prescribing information]. Horsham, PA: Janssen Pharmaceuticals, Inc; January 2017. <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/CONCERTA-pi.pdf> Accessed July 23, 2021.

Conzip® (tramadol hydrochloride) [prescribing information]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC; August 2018. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/022370s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022370s015lbl.pdf) Accessed July 23, 2021.

Cordran® (flurandrenolide) [prescribing information]. Madison, NJ: Allergan USA, Inc.; May 2018. [https://www.allergan.com/assets/pdf/cordran\\_pi](https://www.allergan.com/assets/pdf/cordran_pi) Accessed July 23, 2021.

Cotempla® (methylphenidate extended-release orally disintegrating tablets) [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC; June 2017. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/205489s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205489s000lbl.pdf). Accessed July 23, 2021.

Cozaar® (losartan) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; November 2019. [https://www.merck.com/product/usa/pi\\_circulars/c/cozaar/cozaar\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/c/cozaar/cozaar_pi.pdf) Accessed July 23, 2021.

Crestor® (rosuvastatin) [prescribing information]. Gaithersburg, MD: AstraZeneca Pharmaceuticals LP; September 2020. <https://www.azpicentral.com/crestor/crestor.pdf#page=1> Accessed July 23, 2021.

Cuprimine® (penicillamine) [prescribing information]. Lawrenceville, NJ: Aton Pharma, Inc.; November 2019. <https://www.bauschhealth.com/Portals/25/Pdf/PI/Cuprimine-PI.pdf> Accessed July 23, 2021.

Cutivate® (fluticasone propionate) [prescribing information]. Princeton, NJ: PharmaDerm a division of Fougera Pharmaceuticals Inc. January 2015. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/021152s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021152s004lbl.pdf) Accessed July 23, 2021.

Cymbalta® (duloxetine) [prescribing information]. Indianapolis, IN: Lilly USA, LLC. May 2020. Available at: <http://pi.lilly.com/us/cymbalta-pi.pdf>. Accessed July 23, 2021.

Daypro® (oxaprozin) [prescribing information]. Skokie, IL: G.D. Searle LLC Division of Pfizer Inc; May 2019. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/018841s030lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/018841s030lbl.pdf). Accessed July 23, 2021.

Daytrana® patch (methylphenidate) [prescribing information]. New York, NY: Noven Therapeutics, LLC; October 2019. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/021514s030lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021514s030lbl.pdf). Accessed July 23, 2021.

Dayvigo™ (lemborexant) [prescribing information]. Woodcliff Lake, NJ: Eisai Inc.; April 2020. Available from: <https://www.dayvigohcp.com/-/media/Files/DAYVIGOHCP/PDF/prescribing-information.pdf>. Accessed July 23, 2021.

Derma-Smoothe® (flucinolone acetonide) [prescribing information]. Manasquan, NJ: Royal Pharmaceuticals; 2013. Accessed July 23, 2021.

Desonate® (desonide) [prescribing information]. Wayne, NJ: Bayer Healthcare Pharmaceuticals Inc.; July 2014. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/021844s008lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021844s008lbl.pdf) Accessed July 23, 2021.

Desowen® (desonide) [prescribing information]. Fort Worth, TX: Galderma Laboratories, L.P.; 2015. Accessed July 23, 2021.

Desoxyn® (methamphetamine HCL) [prescribing information]. Lebanon, NJ: Recordati Rare Diseases, Inc; 2017. Accessed July 23, 2021.

Dexedrine® (dextroamphetamine) [prescribing information]. Horsham, PA: Amedra Pharmaceuticals LLC; 2017. July 23, 2021.

Differin® (adapalene) [prescribing information]. Fort Worth, TX: Galderma Laboratories, L.P.; 2015. Accessed July 23, 2021.

Diovan HCT® (valsartan and hydrochlorothiazide) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2020. [https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/diovan\\_hct.pdf](https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/diovan_hct.pdf) Accessed July 23, 2021.

Doral® (quazepam) [prescribing information]. Norcross, GA: Galt Pharmaceuticals LLC; October 2016. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/018708s023lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/018708s023lbl.pdf) Accessed July 23, 2021.

Doryx® (doxycycline hyclate) [prescribing information]. Parsippany, NJ: Warner Chilcott (US), LLC; July 2018. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=99cf2de6-e0a3-42f2-9929-d33e107af948> Accessed July 23, 2021.

Drizalma™ (duloxetine) [package insert] Mohali, India. Sun Pharmaceuticals. June 2020. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=b41423b8-dfec-4d79-ba3c-e43a87803d85&type=display>. Accessed July 23, 2021.

Duac® (clindamycin phosphate and benzoyl peroxide) [prescribing information]. Triangle Park, NC: Stiefel Laboratories; April 2015. [https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Duac/pdf/DUAC-PI-PIL.PDF](https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Duac/pdf/DUAC-PI-PIL.PDF) Accessed July 23, 2021.

Duaklir® (acridinium bromide and formoterol fumarate) [package insert] Morrisville, North Carolina. Circassia, Pharmaceuticals Inc. February 2020. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=bb24d6b0-0d69-4a3c-a7f4-a35ca4804657&type=display>. Accessed July 23, 2021.

Durlaza™ (acetylsalicylic acid) [prescribing information]. New Haven, CT: New Haven Pharmaceuticals, Inc.; September 2015. Accessed July 23, 2021.

[Duragesic \(fentanyl\) Medication Guide](#). Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2019. Available at [www.janssenlabels.com/package-insert/product-monograph/prescribing-information/DURAGESIC-pi.pdf](http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/DURAGESIC-pi.pdf). Accessed July 23, 2021.

Dyanavel® XR (amphetamine) [prescribing information]. Monmouth Junction, NJ: Tris Pharma Inc; February 2019. <http://dyanavelxr.com/pdfs/pi.pdf> Accessed July 23, 2021.

EC-Naprosyn® (naproxen) [prescribing information]. Phoenixville, PA: Genentech, Inc.; 2016. Accessed July 23, 2021.

Ecoza™ (econazole nitrate) [prescribing information]. Florham Park, NJ: Exeltis USA Dermatology, llc; 2016. Accessed July 23, 2021.

Edarbi® (azilsartan kamedoxomil) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, Inc.; March 2020. <https://www.edarbi.com/media/pdf/EDARBI-PI.pdf> Accessed July 23, 2021.

Edarbyclor® (azilsartan kamedoxomil and chlorthalidone) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, Inc.; March 2020. <https://www.edarbi.com/media/pdf/EDARBYCLOR-PI.pdf> Accessed July 23, 2021.

Effexor XR® (venlafaxine hydrochloride) [prescribing information]. Collegeville, PA: Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.; December 2018. <http://labeling.pfizer.com/showlabeling.aspx?ID=100> Accessed July 23, 2021.

Elidel® (pimecrolimus) [prescribing information]. East Hanover, NJ: Novartis; March 2014. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/021302s018lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021302s018lbl.pdf) Accessed July 23, 2021.

Enstilar® (calcipotriene and betamethasone dipropionate) [prescribing information]. Madison, NJ: LEO Pharma Inc.; October 2020. [www.leo-pharma.us/Files/Billeder/US%20Website%20Product%20PIs/Enstilar%20USPI%20-%20Clean%20-%20August%202020%20FINAL.pdf](http://www.leo-pharma.us/Files/Billeder/US%20Website%20Product%20PIs/Enstilar%20USPI%20-%20Clean%20-%20August%202020%20FINAL.pdf). Accessed July 23, 2021.

Entocort EC® (budesonide) [prescribing information]. Allegan, MI: Perrigo; July 2020. Available from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=24f0312f-f768-42db-bf7c-4ba2ee4fc309>. Accessed July 23, 2021.



Ertaczo® (sertaconazole nitrate) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; January 2014. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/021385s005lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021385s005lbl.pdf). Accessed July 23, 2021.

Evoclin® (clindamycin phosphate) [prescribing information]. Newtown, PA: Prestium Pharma, Inc.; August 2018. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/050801s018lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/050801s018lbl.pdf). Accessed July 23, 2021.

Exelderm® (sulconazole nitrate) [prescribing information]. Gurgaon, India: Ranbaxy Laboratories Inc., 2013. Accessed April 5, 2021.

Exforge HCT® (amlodipine valsartan and hydrochlorothiazide) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2020. [https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/exforge\\_hct.pdf](https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/exforge_hct.pdf) Accessed July 23, 2021.

Extavia® (interferon beta-1b) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2020. <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/extavia.pdf> Accessed July 23, 2021.

Eucrisa™ (crisaborole) [prescribing information]. Palo Alto, CA: Anacor Pharmaceuticals, Inc.; April 2020. <http://labeling.pfizer.com/ShowLabeling.aspx?id=5331> Accessed July 23, 2021.

Extina® (ketoconazole) [prescribing information]. Newtown, PA: Prestium Pharma, Inc.; January 2014. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ceae038-9681-45ab-b974-f32b72443022> Accessed July 23, 2021.

Fabior® (tazarotene) [prescribing information]. Greenville, NC: Mayne Pharma; June 2018. Available from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ae0afed7-1d60-45fd-a08b-8db094618521>. Accessed July 23, 2021.

Fanapt® (iloperidone) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2017. Available from: <https://fanaptpro.com/wp-content/uploads/2016/02/Fanapt-Prescribing-Information.pdf>. Accessed July 23, 2021.

Felbatol® (felbamate) [prescribing information]. Somerset, NJ: MEDA Pharmaceuticals, Inc. July 2011. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/020189s027lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020189s027lbl.pdf). Accessed July 23, 2021.

Fenortho™ (fenoprofen) [prescribing information]. Ripley, MS: Sterling-Knight Pharmaceuticals, LLC. March 2017. Accessed July 23, 2021.

Fentora® (fentanyl buccal tablet) [prescribing information]. North Wales, PA: Teva Pharmaceuticals Inc. December 2016. Accessed July 23, 2021.

Fetzima™ (levomilnacipran hydrochloride) [prescribing information]. Parsippany, NJ: Allergan, Inc; October 2019. Available from: [https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/product-prescribing/10092019-FETZIMA-v2\\_OUSPI2220-v2\\_0MG2220-\(clean\).pdf](https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/product-prescribing/10092019-FETZIMA-v2_OUSPI2220-v2_0MG2220-(clean).pdf). Accessed July 23, 2021.

Fiasp® (insulin aspart injection) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; December 2019. Available from: <https://www.novo-pi.com/fiasp.pdf>. Accessed July 23, 2021.

Finacea® (azelaic acid) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc. July 2015. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/207071s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207071s000lbl.pdf) Accessed July 23, 2021.

Fioricet® with codeine (butalbital, acetaminophen, caffeine and codeine phosphate) [prescribing information]. Morristown, NJ. April 2011. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/020232s033lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020232s033lbl.pdf) Accessed July 23, 2021.

Fiorinal® with codeine (butalbital, aspirin, caffeine and codeine phosphate) [prescribing information]. Irvine, CA October 2019. [https://www.allergan.com/assets/pdf/fiorinalwithcodeinespl\\_pi](https://www.allergan.com/assets/pdf/fiorinalwithcodeinespl_pi) Access July 23, 2021.

Focalin XR® (dexamethylphenidate) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2017. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021802s033lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021802s033lbl.pdf) Accessed July 23, 2021.

Follistim® AQ (follitropin) [prescribing information]. Roseland, NJ: Organon USA Inc.; June 2020. [https://www.merck.com/product/usa/pi\\_circulars/f/follistim\\_aq\\_cartridge/follistim\\_cartridge\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/f/follistim_aq_cartridge/follistim_cartridge_pi.pdf) Accessed July 23, 2021.

Fortamet® (metformin hydrochloride) [prescribing information]. Florham Park, NJ: Shionogi Inc.; November 2018. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021574s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021574s020lbl.pdf) Accessed July 23, 2021.

Gemtesa® (vibegron) [prescribing information]. Irvine, CA: Urovant Sciences, Inc.; December 2020. Available from: <https://www.gemtesa.com/sites/default/files/gemtesa-prescribing-information.pdf>. Accessed July 23, 2021.

Gimoti® (metoclopramide) [prescribing information]. Solana Beach, CA: Evoke Pharma, Inc; January 2021. Available from: <https://evokepharma.com/wp-content/uploads/Prescribing-Information-Gimoti%E2%84%A2-metoclopramide-nasal-spray.pdf>. Accessed July 23, 2021.

Gloperba® (colchicine) [prescribing information]. Ferndale, MI: Ferndale Laboratories, Inc. January 2019. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/210942s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/210942s000lbl.pdf). Accessed July 23, 2021.

Glucagen® (glucagon) [prescribing information]. Bagsvaerd, Denmark: Novo Nordisk Inc. June 2020. Available from: <https://www.novo-pi.com/glucagenhypokit.pdf>. Accessed July 23, 2021.

Golytey® (polyethylene glycol 3350 and electrolytes oral solution) [prescribing information]. Holbrook, MA: Braintree Laboratories, Inc.; June 2020. Available from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=57d22b0b-1ae0-4203-babc-f3bac17bd1c9>. Accessed July 23, 2021.

Halcion® (triazolam) [prescribing information]. Kalamazoo, MI: Pharmacia and Upjohn Company LLC; December 2019. <http://labeling.pfizer.com/ShowLabeling.aspx?id=586> Accessed July 23, 2021.

Halog® (halcinonide) [prescribing information]. Gurgaon, India: Ranbaxy Laboratories Inc. November 2019. <https://pi.lilly.com/us/humalog-pen-pi.pdf> Accessed July 23, 2021.

Humalog® (insulin lispro) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; November 2019. Available from: <https://uspi.lilly.com/humalog/humalog.html#pi>. Accessed July 23, 2021.

Humulin® (insulin) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2015. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/020563s172.205747s008lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020563s172.205747s008lbl.pdf). Accessed July 23, 2021.

Hysingla™ ER (hydrocodone bitartrate) [prescribing information]. Stamford, CT: Purdue Pharma L.P.; October 2019. Available from: [app.purduepharma.com/xmlpublishing/pi.aspx?id=h](http://app.purduepharma.com/xmlpublishing/pi.aspx?id=h). Accessed July 23, 2021.

Hyzaar® (losartan potassium and hydrochlorothiazide) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; November 2019. [https://www.merck.com/product/usa/pi\\_circulars/h/hyzaar/hyzaar\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/h/hyzaar/hyzaar_pi.pdf) Accessed July 23, 2021.

Ilevro® (nepafenac ophthalmic suspension) [prescribing information]. Fort Worth, Texas: Alcon Laboratories, Inc. January 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6c212466-ff8d-ecfc-ede2-ef8bdcaaf114>. Accessed July 23, 2021.

Inderal® LA (propranolol hydrochloride) [prescribing information]. Cranford, NJ: Akrimax Pharmaceuticals LLC; November 2017. <http://labeling.pfizer.com/ShowLabeling.aspx?id=9895> Accessed July 23, 2021.

Intuniv® ER (guanfacine HCL) [prescribing information]. Exton, PA: Shire US Manufacturing Inc.; December 2019. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/022037s019lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022037s019lbl.pdf). Accessed July 23, 2021.

Invega® (paliperidone) [prescribing information]. Raritan, NJ: Janssen Pharmaceuticals, Inc.; January 2019. Available from: <https://www.invega.com/prescribing-information.html>. Accessed April 5, 2021.



Invokamet® XR (canagliflozin and metformin hydrochloride) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. August 2020. Available from: <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVOKAMET+XR-pi.pdf>. Accessed July 23, 2021.

Invokana® (canagliflozin) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. August 2020. Available from: <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVOKANA-pi.pdf>. Accessed July 23, 2021.

Jentadueto® (litagliptan and metformin hydrochloride) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; March 2020. <http://bidocs.boehringer-ingelheim.com/BIWebAccess/ViewServlet.ser?docBase=renetnt&folderPath=/Prescribing+Information/PIs/Jentadueto/Jentadueto.pdf> Accessed July 23, 2021.

Kadian® (morphine sulfate) [prescribing information]. Madison, NJ: Allergan USA, Inc.; October 2019. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/020616s063lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020616s063lbl.pdf). Accessed July 23, 2021.

Kapspargo® (metoprolol succinate) [prescribing information]. New Brunswick, NJ. May 2018. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/210428s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210428s001lbl.pdf). Accessed July 23, 2021.

Kapvay™ (clonidine) [prescribing information]. Oakville, Ontario: Concordia Pharmaceuticals Inc.; February 2020. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/022331s021lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022331s021lbl.pdf). Accessed July 23, 2021.

Kazano® (alogliptan and metformin hydrochloride) [prescribing information]. Lake County, IL: Takeda Pharmaceuticals America, Inc.; June 2019. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/203414s012lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203414s012lbl.pdf). Accessed July 23, 2021..

Kenalog® (triamcinolone acetonide) [prescribing information]. Gurgaon, India: Ranbaxy Laboratories Inc., June 2018. [https://packageinserts.bms.com/pi/pi\\_kenalog-40.pdf](https://packageinserts.bms.com/pi/pi_kenalog-40.pdf) Accessed July 23, 2021.

Keppra® (levetiracetam) [prescribing information]. Smyrna, GA: UCB Inc.; October 2017. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021035s100,021505s040lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021035s100,021505s040lbl.pdf). Accessed July 23, 2021.

Ketoprofen [prescribing information]. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=198a4140-f4c0-4478-9157-ee1d68d0bb96>. Accessed July 23, 2021.

Khedeza™ (desvenlafaxine) [prescribing information]. Morristown, NJ: Pernix Therapeutics; January 2019. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/204683s006lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/204683s006lbl.pdf) Accessed July 23, 2021.

Klonopin® (clonazepam) [prescribing information]. San Francisco, CA: Genentech USA, Inc. October 2017. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/017533s059lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017533s059lbl.pdf). Accessed July 23, 2021.

Kristalose® packet (lactulose) [prescribing information]. Nashville, TN: Cumberland Pharmaceuticals Inc. July 2018. Available at: [http://www.kristalose.com/wp-content/uploads/2019/03/Kristalose\\_PI\\_July\\_2018.pdf](http://www.kristalose.com/wp-content/uploads/2019/03/Kristalose_PI_July_2018.pdf). Accessed July 23, 2021.

Lamictal® (lamotrigine) [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; February 2020. [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Lamictal/pdf/LAMICTAL-PI-MG.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Lamictal/pdf/LAMICTAL-PI-MG.PDF) Accessed July 23, 2021.

Latuda® (lurasidone hydrochloride) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; December 2019. <https://www.latuda.com/LatudaPrescribingInformation.pdf> Accessed July 23, 2021.

Lazanda® [package insert]. Bedminster, NJ: Archimedes Pharma US Inc. February 2020. Available at <https://lazanda.com/Docs/Lazanda-PI-0220.pdf>. Accessed July 23, 2021.

Lexapro® (escitalopram) [prescribing information]. Parsippany, NJ: Allergan, Inc; January 2017. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021323s047lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021323s047lbl.pdf). Accessed July 23, 2021.

Lexette® (halobetasole propionate) [prescribing information]. Greenville, NC: Mayne Pharma. May 2020. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d5d0d307-37ad-4714-ba3f-5343672bc0e7>. Accessed July 23, 2021.

Lidoderm® (lidocaine) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc.; November 2018. [http://www.endo.com/File%20Library/Products/Prescribing%20Information/LIDODERM\\_prescribing\\_information.html](http://www.endo.com/File%20Library/Products/Prescribing%20Information/LIDODERM_prescribing_information.html) Accessed July 23, 2021.

Lipitor® (atorvastatin) [prescribing information]. Collegeville, PA: Parke-Davis Div of Pfizer Inc; November 2019. <http://labeling.pfizer.com/ShowLabeling.aspx?id=587> Accessed July 23, 2021.

Livalo® (pitavastatin) [prescribing information]. Montgomery, AL: Kowa Pharmaceuticals America, Inc.; September 2020. [https://www.kowapharma.com/documents/LIVALO\\_PI\\_CURRENT.pdf](https://www.kowapharma.com/documents/LIVALO_PI_CURRENT.pdf) Accessed July 23, 2021.

Locoid® (hydrocortisone butyrate) [prescribing information]. Cumberland, RI: Onset Dermatologics LLC; November 2014. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/020769s014lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020769s014lbl.pdf) Accessed July 23, 2021.

Lonhala™ Magnair (glycopyrrolate) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals, Inc; August 2020. <https://www.lonhalamagnair.com/LonhalaMagnair-Prescribing-Information.pdf> Accessed July 23, 2021.

Loprox® (ciclopirox) [prescribing information]. Fairfield, NJ: Medimetriks Pharmaceuticals, Inc.; 2016. Accessed July 23, 2021.

Lorzone® (chlorzoxazone) [prescribing information]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC; October 2018. Accessed July 23, 2021.

Lotrel® (amlodipine and benazepril) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; April 2021. Available from: <https://www.novartis.us/sites/www.novartis.us/files/lotrel.pdf>. Accessed July 23, 2021.

Lotronex® (alosetron hydrochloride) [prescribing information]. Roswell, GA: Sebela Pharmaceuticals Inc. January 2019. Available from: [https://www.lotronex.com/hcp\\_docs/PI%20v.Sebela\\_Final.pdf](https://www.lotronex.com/hcp_docs/PI%20v.Sebela_Final.pdf). Accessed July 23, 2021.

Lovaza® (omega-3-acid ethyl esters) [prescribing information]. Research Triangle Park, NC. GlaxoSmithKline; April 2019. [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Lovaza/pdf/LOVAZA-PI-PIL.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Lovaza/pdf/LOVAZA-PI-PIL.PDF) Accessed July 23, 2021.

Lunesta® (eszopiclone) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; August 2019. <http://www.lunesta.com/PostedApprovedLabelingText.pdf> Accessed July 23, 2021.

Luxiq® (betamethasone valerate) [prescribing information]. Newtown, PA: Prestium Pharma, Inc.; May 2014. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=51fe8c40-5e56-4449-8995-f227c8bb5a50> Accessed July 23, 2021.

Luzu® (luliconazole) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; April 2020. <https://www.bauschhealth.com/Portals/25/Pdf/PI/Luzurx-PI.pdf> Accessed July 23, 2021.

Lyumjev® (insulin lispro-aabc) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; June 2020. Available from: <https://pi.lilly.com/us/lyumjev-uspi.pdf?s=pi>. Accessed July 23, 2021.

Mavenclad® (cladribine) [prescribing information]. Rockland, MA: EMD Serono, Inc. April 2019. Available at: <https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/pi/mavenclad-pi.pdf>. Accessed July 23, 2021.

Menopur® (menotropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; May 2019. [www.ferringusa.com/wp-content/uploads/2019/04/Menopur-PI-Rev.-05.2018-20Mar2019.pdf](http://www.ferringusa.com/wp-content/uploads/2019/04/Menopur-PI-Rev.-05.2018-20Mar2019.pdf). Accessed July 23, 2021.

Metadate CD® (methylphenidate HCL) [prescribing information]. Rochester, NY: Unither Manufacturing, LLC; 2016. Accessed July 23, 2021.

Micardis® HCT (telmisartan and hydrochlorothiazide) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; February 2018. <https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Micardis%20HCT/MicardisHCT-US2.PDF> Accessed July 23, 2021.

Minocin® (minocycline hydrochloride) [prescribing information]. Cumberland, RI: Onset Dermatologics LLC; 2017. Accessed July 23, 2021.

Minolira™ (minocycline hydrochloride extended release) [prescribing information]. Princeton, NJ. Promius Pharma, LLC. May 2017. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/209269s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209269s000lbl.pdf). Accessed July 23, 2021.

Mirvaso® (brimonidine) [prescribing information]. Fort Worth, TX: Galderma Laboratories, L.P. November 2017. <https://www.galderma.com/us/sites/g/files/jcdfhc341/files/2018-11/MirvasoPI.pdf> Accessed July 23, 2021.

Mitigare® (colchicine) [prescribing information]. Memphis, TN: Hikma Americas Inc.; July 2019. <https://www.mitigare.com/wp-content/uploads/mitigare-pi.pdf> Accessed July 23, 2021.

MS Contin (morphine sulfate) [prescribing information]. Stamford, CT: Purdue Pharma L.P.; October 2019. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/019516s055lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/019516s055lbl.pdf). Accessed July 23, 2021.

Mobic® (meloxicam) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; February 2020. <https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Mobic/MobicTabs7-5-15mg.PDF> Accessed July 23, 2021.

Morphabond ER [package insert]. Parsippany, NJ. Daiichi Sankyo, Inc. October 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1806c935-0a76-4f6a-80c8-4aee8a95cb7d&type=display#section-2>. Accessed July 23, 2021.

Monodox® (doxycycline) [prescribing information]. West Chester, PA: Aqua Pharmaceuticals; April 2017. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/050641s029lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/050641s029lbl.pdf). Accessed July 23, 2021.

Motegrity™ (prucalopride) [prescribing information]. Lexington, MA: Shire US Inc. November 2020. Available from: [https://www.shirecontent.com/PI/PDFs/MOTTEGRITY\\_USA\\_ENG.pdf](https://www.shirecontent.com/PI/PDFs/MOTTEGRITY_USA_ENG.pdf). Accessed July 23, 2021.

Movantik® (naloxegol) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. April 2020. Available from: <https://www.azpicentral.com/movantik/movantik.pdf#page=1>. Accessed July 23, 2021.

Moviprep® (polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate, and ascorbic acid for oral solution) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, LLC; May 2019. Available from: <https://shared.salix.com/shared/pi/moviprep-pi.pdf?id=8251081>. Accessed July 23, 2021.

Mytesi™ (crofelemer) [prescribing information]. San Francisco, CA: Napo Pharmaceuticals, Inc.; November 2020. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/202292s006lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202292s006lbl.pdf). Accessed July 23, 2021.

Nalfon® (fenoprofen) [prescribing information]. Ridgeland, MS: Xspire Pharma. June 2016. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/017604s046lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/017604s046lbl.pdf) Accessed July 23, 2021.

Naprelan® CR (naproxen) [prescribing information]. Florham Park, NJ: Shionogi Inc.; September 2017. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/020353s034lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020353s034lbl.pdf) Accessed July 23, 2021.

Naprosyn® (naproxen) [prescribing information]. Phoenixville, PA: Genentech, Inc.; March 2017. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/017581s113.018164s063.020067s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017581s113.018164s063.020067s020lbl.pdf) Accessed July 23, 2021.

Nalocet® (oxycodone and acetaminophen tablets) [prescribing information]. Las Vegas, NV. Forte Bio-Pharma LLC. December 2020. Available from: <https://fortebiopharma.com/wp-content/uploads/2021/01/Nalocet-PI.pdf>. Accessed July 23, 2021.

Nesina® (alogliptan) [prescribing information]. Lake County, IL: Takeda Pharmaceuticals America, Inc.; June 2019. <https://general.takedapharm.com/NESINAPI> Accessed July 23, 2021.

Neurontin® (gabapentin) [prescribing information]. New York, NY: Parke-Davis of Pfizer, Inc. April 2020. Available from: <http://labeling.pfizer.com/ShowLabeling.aspx?id=630>. Accessed July 23, 2021.

Nevanac® (nepafenac ophthalmic suspension) [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc. December 2017. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021862s013lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021862s013lbl.pdf). Accessed July 23, 2021.

Niaspan® (niacin extended-release tablets) [prescribing information]. North Chicago, IL: AbbVie Inc. September 2020. Available at: <https://www.rxabbvie.com/pdf/niaspan.pdf>. Accessed July 23, 2021.

Noritate® (metronidazole cream) [prescribing information]. Bridgewater, NJ: Dermik Laboratories. March 2018. July 23, 2021.

Norvasc® (amlodipine besylate) [prescribing information]. New York, NY: Pfizer, Inc. March 2017. Available at: <http://labeling.pfizer.com/ShowLabeling.aspx?id=562>. Accessed July 23, 2021.

Nulytely® (polyethylene glycol 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) [prescribing information]. Braintree, MA: Braintree Laboratories, Inc.; May 2020. Available from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e7cf708c-937e-4aae-ab0a-0361c144a256>. Accessed July 23, 2021.

Nuvigil® (armodafinil) [prescribing information]. North Wales, PA: Teva Pharmaceuticals. November 2018. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021875s023lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021875s023lbl.pdf) Accessed July 23, 2021.

Olux®/ Olux-E® (clobetasol propionate) [prescribing information]. Newtown, PA: Prestium Pharma, Inc.; April 2018. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/021142s022lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021142s022lbl.pdf) Accessed July 23, 2021.

Orfadin® (nitisinone) [prescribing information]. Sweden: Apotek Produktion & Labroatorier AB. May 2019. Available at: <https://www.orfadin.com/pdf/full-prescribing-information.pdf>. Accessed July 23, 2021.

Ortikos™ (budesonide extended-release) [prescribing information]. Gujarat, India: Sun Pharmaceuticals Industries Ltd.; October 2019. Available from: [www.ferringusa.com/wp-content/uploads/2020/07/Ortikos-PI\\_6794-02.pdf](http://www.ferringusa.com/wp-content/uploads/2020/07/Ortikos-PI_6794-02.pdf). Accessed July 23, 2021.

Oseni® (alogliptan and pioglitazone) [prescribing information]. Lake County, IL: Takeda Pharmaceuticals America, Inc.; June 2019. <https://general.takedapharm.com/OSENIPI> Accessed July 23, 2021.

Osmoprep® (sodium phosphate monobasic monohydrate and sodium phosphate dibasic anhydrous) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, LLC; March 2019. Available from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b46c0b17-c49b-4791-913f-3e6e1fdb88e>. Accessed July 23, 2021.

Oxistat® (oxiconazole) [prescribing information]. Princeton, NJ: PharmaDerm a division of Fougera Pharmaceuticals Inc.; 2012. Accessed July 23, 2021.

Oxtellar XR® (oxcarbazepine extended-release) [prescribing information]. Ontario, Canada; Patheon Inc. December 2018. Available from: <https://oxtellarxr.com/assets/OxtellarXRPrescribingInformation.pdf>. Accessed July 23, 2021.

Oxycodone Oral Solution – VistaPharm Medication Guide. Available at <http://online.factsandcomparisons.com/MedGuide/597240.pdf>. Accessed July 23, 2021.

Ozempic® (semaglutide) [prescribing information]. Plainsboro, NJ. Novo Nordisk Inc. September 2020. <https://www.novo-pi.com/ozempic.pdf> Accessed July 23, 2021.

Ozobax™ (baclofen) [package insert]. Athens, Georgia: Metacel Pharmaceuticals, LLC.; May 2020. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=92153f69-bc9b-4bef-9a8e-751effde5c7e&type=display>. Accessed July 23, 2021.

Pamelor™ (nortriptyline) [prescribing information]. Hazelwood, MO: Mallinckrodt Inc. October 2012. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/018012s029,018013s061lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/018012s029,018013s061lbl.pdf). Accessed July 23, 2021.

Pancreaze® (pancrelipase) [prescribing information]. Campbell, CA: Vivus, Inc. March 2020. Available at: <https://pancreaze.com/wp-content/uploads/2018/12/PANCREAZE-pi.pdf>. Accessed July 23, 2021.

Pandel® (hydrocortisone probutate) [prescribing information]. Princeton, NJ: PharmaDerm a division of Fougera Pharmaceuticals Inc.; April 2020. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=361338e6-d719-4bea-aca0-7dd591fca08> Accessed July 23, 2021.

Pepcid® (famotidine) [prescribing information]. Bridgewater, NJ: Valent Pharmaceuticals North America LLC; November 2018. Available from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a06502d9-7903-4f37-833e-e5763d502def>. Accessed July 23, 2021.

Pertzye® (pancrelipase) [prescribing information]. Bethlehem, PA: Digestive Care, Inc. March 2020. Available at: [https://resources.chiesiusa.com/Pertzye/PERTZYE\\_PI.pdf](https://resources.chiesiusa.com/Pertzye/PERTZYE_PI.pdf). Accessed July 23, 2021.

Plenvu® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, LLC; May 2019. Available from: <https://shared.salix.com/shared/pi/plenvu-pi.pdf>. Accessed July 23, 2021.

Ponvory® (ponesimod) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021. Available at: <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PONVORY-pi.pdf>. Accessed July 23, 2021.

Primlev® (oxycodone/acetaminophen) [prescribing information]. Cranford, NJ: Akrimax Pharmaceuticals, LLC. July 2017. Available at: <https://www.primlev.com/wp-content/documents/Primlev-PI.pdf>. Accessed July 23, 2021.

Prinivil® (lisinopril) [prescribing information]. Whitehouse Station, NJ. Merck&Co., Inc. November 2019. Available at: [https://www.merck.com/product/usa/pi\\_circulars/p/prinivil/prinivil\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/p/prinivil/prinivil_pi.pdf). Accessed July 23, 2021.

Pristiq® (desvenlafaxine succinate) [prescribing information]. Collegeville, PA: Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.; November 2018. Available from: <http://labeling.pfizer.com/showlabeling.aspx?id=497>. Accessed July 23, 2021.

Proair Digihaler (albuterol sulfate) [prescribing information]. Frazer, PA: Teva Respiratory LLC. September 2020. Available at: [https://www.proairdigihaler.com/globalassets/proair\\_digihaler/Proair\\_Digihaler\\_PI.pdf](https://www.proairdigihaler.com/globalassets/proair_digihaler/Proair_Digihaler_PI.pdf). Accessed July 23, 2021.

Protopic® (tacrolimus) [prescribing information]. Deerfield, IL: Astellas Pharma US, Inc; November 2011. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2011/050777s018lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/050777s018lbl.pdf) Accessed July 23, 2021.

Product Information: EXALGO(R) oral extended-release tablets, hydromorphone HCl oral extended-release tablets. Mallinckrodt Brand Pharmaceuticals, Inc. (per FDA), Hazelwood, MO, 2015. Micromedex website [Exalgo]. Available at [www.micromedex.com](http://www.micromedex.com). Accessed July 23, 2021.

Product Information: ZOXYDRO(R) ER oral extended-release capsules, hydrocodone bitartrate oral extended-release capsules. Pernix Therapeutics, LLC. (per FDA), Morristown, NJ, 2016. Accessed July 23, 2021.

Prolate™ (oxycodone and acetaminophen) [prescribing information]. Las Vegas, NV: Forte Bio-Pharma LLC; January 2020. Available from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9cbbfa94-37b9-9652-e053-2995a90a736b>. Accessed July 23, 2021.

Proventil® (albuterol) [prescribing information]. Kenilworth, NJ: Merck Sharp & Dohme Corp; September 2017. [https://www.merck.com/product/usa/pi\\_circulars/p/proventil\\_hfa/proventil\\_hfa\\_doseindicator\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/p/proventil_hfa/proventil_hfa_doseindicator_pi.pdf) Accessed July 23, 2021.

Prozac® (fluoxetine hydrochloride) [prescribing information]. Indianapolis, IN: Dista Products Company; April 2020. <http://pi.lilly.com/us/prozac.pdf> Accessed July 23, 2021.

Provigil® (modafinil) [prescribing information]. Fazer, PA: Cephalon, Inc., January 2015.  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/020717s037s038lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020717s037s038lbl.pdf) Accessed July 23, 2021.

Qtern® (dapagliflozin and saxagliptin) [prescribing information]. Wilmington DE, AstraZeneca Pharmaceuticals LP. January 2020.  
<https://www.azpicentral.com/qtern/qtern.pdf#page=1> Accessed July 23, 2021.

Qudexy® XR (topiramate extended release) [prescribing information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC. February 2020. Available from: [www.upsher-smith.com/wp-content/uploads/QXR-MktgInsert.pdf](http://www.upsher-smith.com/wp-content/uploads/QXR-MktgInsert.pdf). Accessed July 23, 2021.

Quillichew ER™ (methylphenidate) [prescribing information]. Cupertino, CA: NextWave Pharmaceuticals, Inc.; August 2018.  
<http://labeling.pfizer.com/ShowLabeling.aspx?id=2577> Accessed July 23, 2021.

Quillivant XR® (methylphenidate) [prescribing information]. Cupertino, CA: NextWave Pharmaceuticals, Inc.; August 2018.  
<http://labeling.pfizer.com/showlabeling.aspx?id=965> Accessed July 23, 2021.

Qvar Redihaler® (beclomethasone dipropionate HFA) [prescribing information]. Frazer, PA: Teva Respiratory, LLC. January 2021.  
Available from: <https://www.qvar.com/globalassets/qvar/qvar-redihaler-pi.pdf>. Accessed July 23, 2021.

Rayaldee® (calcifediol) [prescribing information]. Miami, FL: OPKO Pharmaceuticals LLC; December 2019.  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/208010s005lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208010s005lbl.pdf). Accessed July 23, 2021.

Rebif® (interferon beta-1a) [prescribing information]. Billerica, MA: EMD Serono, Inc.; October 2020.  
<https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/pi/rebif-pi.pdf> Accessed July 23, 2021.

Relafen DS™ (nabumetone) [package insert] Hazlet, New Jersey. Carwin Pharmaceutical Associates, LLC. January 2020. Available at <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a9a0af85-6c43-4a2d-ba75-0be4ca64c931&type=display>. Accessed February 22, 2021.

Relistor® (methylalntrexone) [prescribing information]. Raleigh, NC: Salix Pharmaceuticals, Inc.; April 2020.  
<https://shared.salix.com/shared/pi/relistor-pi.pdf?id=8251081> Accessed July 23, 2021.

Reltone™ (ursodiol capsules) [prescribing information]. Las Vegas, NV. Intra-Sana Laboratories LLC; November 2020. Available at: <https://intrasanalaboratories.com/wp-content/uploads/2021/07/Reltone-PI-02-17-21.pdf>. Accessed July 23, 2021.

Rescula® (unoprostone isopropyl) [prescribing information]. Rockville, MD: Sucampo Pharma Americas, LLC; 2013. Accessed July 23, 2021.

Restoril™ (temazepam) [prescribing information]. UK: Mallinckrodt, Inc September 2016.  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/018163s064lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/018163s064lbl.pdf) Accessed July 23, 2021.

Retin-A® (tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2016. Accessed July 23, 2021.

Retin-A Micro® (tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2016. Accessed July 23, 2021.

Rexulti™ (brexipiprazole) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; March 2020.  
<https://www.otsuka-us.com/media/static/Rexulti-PI.pdf> Accessed July 23, 2021.

Rhofade® (oxymetazoline) [prescribing information]. Irvine CA: Allergan. November 2019. Available from: [https://www.allergan.com/assets/pdf/rhofade\\_pi.pdf](https://www.allergan.com/assets/pdf/rhofade_pi.pdf). Accessed July 23, 2021.

Ritalin LA® (methylphenidate HCL) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2019. [https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/ritalin\\_la.pdf](https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/ritalin_la.pdf) Accessed July 23, 2021.



Rybelsus™ (semaglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc. January 2020. <https://www.novo-pi.com/rybelsus.pdf>. Accessed July 23, 2021.

Rytary™ (levodopa and carbidopa) [prescribing information]. Hayward, CA: Impax Specialty Pharma; December 2019. <http://documents.impaxlabs.com/rytary/pi.pdf> Accessed July 23, 2021.

Saphris® (asenapine maleate) [prescribing information]. Parsippany, NJ: Allergan USA, Inc.; February 2017. [https://www.allergan.com/assets/pdf/saphris\\_pi](https://www.allergan.com/assets/pdf/saphris_pi) Accessed July 23, 2021.

Secuado® (asenapine film) [prescribing information]. Japan: Hisamitsu Pharmaceutical Co., Inc. October 2019. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=685eaf44-5944-4f38-afba-0a4fc0b3462b&type=display>. Accessed July 23, 2021.

Seebri® (glycopyrrolate) [prescribing information]. Marlborough MA: Sunovion Pharmaceuticals Inc. January 2018. Available at: <https://www.seebri.us/Seebri-Prescribing-Information.pdf>. Accessed July 23, 2021.

Segluromet™ (ertuglifozin and metformin hydrochloride) [prescribing information]. Whitehouse Station, NJ. Merck & Co., Inc. February 2021. [https://www.merck.com/product/usa/pi\\_circulars/s/segluromet/segluromet\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/s/segluromet/segluromet_pi.pdf) Accessed July 23, 2021.

Semglee™ (insulin glargine injection) [prescribing information]. Morgantown, WV: Mylan Specialty L.P.; June 2020. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?type=display&setid=970259e5-179a-4116-9d09-f3f8ad052283>. Accessed July 23, 2021.

Seysara™ (sarecycline) [prescribing information]. Exton, PA: Almirall, Inc. June 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/209521s007lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209521s007lbl.pdf). Accessed July 23, 2021.

Silenor® (doxepin) [prescribing information]. Morristown, NJ: Pernix Therapeutics; August 2019. <https://www.silenor.com/Content/pdf/prescribing-information.pdf> Accessed July 23, 2021.

Skelaxin® (metaxalone) [prescribing information]. Collegeville, PA: Pfizer Laboratories Div Pfizer Inc; 2017. Accessed July 23, 2021.

Solodyn® (minocycline) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; September 2017. <https://www.bauschhealth.com/Portals/25/Pdf/PI/Solodyn-PI.Pdf> Accessed July 23, 2021.

Soma® (carisprodol) [prescribing information]. Somerset, NJ: Meda Pharmaceuticals Inc.; 2013. Accessed July 23, 2021.

Sonata® (zaleplon) [prescribing information]. Collegeville, PA: Pfizer Laboratories Div Pfizer Inc; August 2019. Accessed July 23, 2021.

Soolantra® (ivermectin) [prescribing information]. Fort Worth, TX: Galderma Laboratories, L.P. July 2018. [https://www.galderma.com/us/sites/g/files/jcdfhc341/files/2019-01/Soolantra\\_Cream\\_PI.pdf](https://www.galderma.com/us/sites/g/files/jcdfhc341/files/2019-01/Soolantra_Cream_PI.pdf) Accessed July 23, 2021.

Steglatro™ (ertuglifozin) [prescribing information]. Whitehouse Station, NJ. Merck & Co., Inc. February 2021. [https://www.merck.com/product/usa/pi\\_circulars/s/steglatro/steglatro\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/s/steglatro/steglatro_pi.pdf) Accessed July 23, 2021.

Steglujan™ (ertuglifozin and sitagliptin) [prescribing information]. Whitehouse Station, NJ. Merck & Co., Inc. February 2021. [https://www.merck.com/product/usa/pi\\_circulars/s/steglujan/steglujan\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/s/steglujan/steglujan_pi.pdf) Accessed July 23, 2021.

Strattera® (atomoxetine) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; February 2020. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/021411s049lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021411s049lbl.pdf). Accessed July 23, 2021.

Subsys® (fentanyl sublingual spray). [prescribing information]. Chandler, AZ: Insys Therapeutics, Inc. December February 2020. [https://www.subsys.com/assets/subsys/client\\_files/files/PrescribingInfo.pdf](https://www.subsys.com/assets/subsys/client_files/files/PrescribingInfo.pdf) Accessed July 23, 2021.

SymlynPen® (pramlintide acetate) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2019. <https://www.azpicentral.com/symlyn/symlyn.pdf#page=1> Accessed July 23, 2021.

Synlar® (fluocinolone acetonide) [prescribing information]. Mahwah, NJ: Glenmark Pharmaceuticals; 2017. Accessed July 23, 2021.

Syprine® (trientine hydrochloride) [prescribing information], Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; December 2016. Available from: <https://www.bauschhealth.com/Portals/25/Pdf/PI/Syprine-PI.pdf>. Accessed July 23, 2021.

Taclonex® (calcipotriene and betamethasone dipropionate) [prescribing information]. Madison, NJ: LEO Pharma Inc.; July 2019. Available from: <https://www.leo-pharma.us/Files/Billeder/US%20Website%20Product%20PIs/TTS%20-%20USPI%20-%20%20Rev%20July%202019%20FINAL.pdf>. Accessed July 23, 2021.

Targadox™ (doxycycline) [prescribing information]. Scottsdale, AZ: Journey Medical Corporation; 2016. Accessed July 23, 2021.

Tazorac® (tazorotene) [prescribing information]. Irvine, CA: Allergan. July 2017. Accessed July 23, 2021.

Tekturna HCT® (aliskiren hemifumarate and hydrochlorothiazide) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019. Available from: [https://www.tekturna.com/wp-content/uploads/2020/08/TekturnaHCT\\_PCR-1.pdf](https://www.tekturna.com/wp-content/uploads/2020/08/TekturnaHCT_PCR-1.pdf). Accessed July 23, 2021.

Tegretol® (carbamazepine) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. February 2019. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/016608s101,018281s048lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/016608s101,018281s048lbl.pdf). Accessed July 23, 2021.

Tegretol® XR (carbamazepine extended-release) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. February 2019. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/016608s101,018281s048lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/016608s101,018281s048lbl.pdf). Accessed July 23, 2021.

Tenoretic® (atenolol and chlorthalidone) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2017. Accessed July 23, 2021.

Tenormin® (atenolol) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2017. Accessed July 23, 2021.

Thyquidity™ (levothyroxine sodium oral solution) [prescribing information]. Largo, FL: VistaPharm, inc.; December 2020. Available from: <https://www.thyquidity.com/pdf/Prescribing-Information.pdf>. Accessed July 23, 2021.

Tirosint (levothyroxine sodium) [prescribing information]. Lugano, Switzerland. Institut Biochimique SA. June 2018. <https://tirosint.com/wp-content/uploads/2019/04/Tirosint-PI.pdf>. Accessed July 23, 2021.

Tivorbex™ (indomethacin) [prescribing information]. Philadelphia, PA: Iroko Pharmaceuticals, LLC. February 2014. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/204768s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204768s000lbl.pdf). Accessed July 23, 2021.

Topamax® (topiramate capsules) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; May 2017. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/020505s057\\_020844s048lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020505s057_020844s048lbl.pdf) Accessed July 23, 2021.

Topicort® (desoximetasone) [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals U.S.A., Inc.; 2016. Accessed July 23, 2021.

Toviaz® (fesoterodine fumarate) [prescribing information]. Collegeville, PA: Pfizer Laboratories Div Pfizer Inc; November 2017. <http://labeling.pfizer.com/showlabeling.aspx?id=540> Accessed July 23, 2021.

Tradjenta® (linagliptan) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; March 2020. [https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Tradjenta/Tradjenta.pdf?DMW\\_FORMAT=pdf](https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Tradjenta/Tradjenta.pdf?DMW_FORMAT=pdf) Accessed July 23, 2021.



Travatan Z® (travoprost) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2020. Available from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=028455e0-ae77-4213-8819-3b58ef7d6a14>. Accessed July 23, 2021.

Trianex® (triamcinolone acetonide ointment) [prescribing information]. Farmville, NC: CPM Pharma, Inc. April 2019. Available from: [https://www.trianexointment.com/wp-content/themes/bridge-child/docs/TRIANEX\\_Prescribing%20Information.pdf](https://www.trianexointment.com/wp-content/themes/bridge-child/docs/TRIANEX_Prescribing%20Information.pdf). Accessed July 23, 2021.

Tribenzor® (olmesartan medoxomil/amlodipine/hydrochlorothiazide) [prescribing information]. Parsippany, NJ: Daiichi Sankyo, Inc.; May 2020. <https://dsi.com/prescribing-information-portlet/getPIContent?productName=Tribenzor&inline=true> Accessed July 23, 2021.

Trintellix™ (vortioxetine) [prescribing information]. Lake County, IL: Takeda Pharmaceuticals America, Inc.; January 2021. <https://general.takedapharm.com/TRINTELLIXPI> Accessed July 23, 2021.

Trokendi XR® (topiramate ER capsules) [prescribing information]. Winchester, KY: Catalent Pharma Solutions. November 2020. Available from: <https://www.trokendixr.com/assets/TrokendiXRPrescribingInformation.pdf>. Accessed July 23, 2021.

Trulance™ (plecanatide) [prescribing information]. New York, NY: Synergy Pharmaceuticals Inc.; October 2020. <https://www.bauschhealth.com/Portals/25/Pdf/PI/trulance-pi.pdf>. Accessed July 23, 2021.

Tudorza® (acclidinium bromide inhalation powder) [prescribing information]. St. Louis, MO: Forest Pharmaceuticals, Inc. April 2019. <https://www.tudorza.com/pdf/tudorza-pressair-prescribing-information.pdf>. Accessed July 23, 2021.

Twynsta® (telmisartan/amlodipine) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; February 2018. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/022401s019lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022401s019lbl.pdf). Accessed July 23, 2021.

Uceris® (budesonide) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, LLC; April 2020. Available from: <https://shared.salix.com/shared/pi/uceris-pi.pdf>. Accessed July 23, 2021.

Uloric® (allopurinol) [prescribing information]. Lake County, IL: Takeda Pharmaceuticals America, Inc.; February 2019. Available from: <https://general.takedapharm.com/ULORICPI>. Accessed July 23, 2021.

Ultracet® (tramadol hydrochloride and acetaminophen) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. October 2019. <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ULTRACET-pi.pdf> Accessed July 23, 2021.

Ultram® (tramadol hydrochloride) [prescribing information]. Raritan, NJ: Ortho-McNeil Pharmaceutical, Inc. August 2017. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021692s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021692s015lbl.pdf) Accessed July 23, 2021.

Ultravate® (halobetasol propionate) [prescribing information]. Gurgaon, India: Ranbaxy Laboratories Inc., November 2015. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/208183s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208183s000lbl.pdf) Accessed July 23, 2021.

US Food and Drug Administration (FDA): FDA Drug Safety Communication: FDA warns about several safety issues with opioid pain medicines; requires label changes. US Food and Drug Administration (FDA). Silver Spring, MD. 2016. Available at: <https://www.fda.gov/Drugs/DrugSafety/ucm489676.htm>. Accessed July 23, 2021.

Utibron™ Neohaler® (indacaterol and glycopyrrolate) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019. <https://www.utibron.com/Utibron-Prescribing-Information.pdf> Accessed July 23, 2021.

Valium® (diazepam) [prescribing information]. Nutley, NJ: Roche Laboratories Inc.; 2017. Accessed July 23, 2021.

Valtrex® (valacyclovir hydrochloride) [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; 2013. Accessed July 23, 2021.

Vanatol LQ/S (butalbital, acetaminophen and caffeine) [prescribing information]. Arlington, TX: GM Pharmaceuticals, Inc. Accessed July 23, 2021.

Vanos® (fluocinonide) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2017. Accessed July 23, 2021.

Vasotec® (enalapril) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2017. Accessed July 23, 2021.

Vecamyl™ (mecamylamine) [prescribing information]. Manchester, MO: Manchester Pharmaceuticals; 2015. Accessed July 23, 2021.

Veltin® (clindamycin phosphate and tretinoin) [prescribing information]. West Chester, PA: Aqua Pharmaceuticals; 2016. Accessed July 23, 2021.

Ventolin® (albuterol) [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; February 2021.  
[https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Ventolin\\_HFA/pdf/VENTOLIN-HFA-PI-PIL.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Ventolin_HFA/pdf/VENTOLIN-HFA-PI-PIL.PDF) Accessed July 23, 2021.

Verdeso® (desonide) [prescribing information]. West Chester, PA: Aqua Pharmaceuticals; April 2019.  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/021978s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021978s015lbl.pdf). Accessed July 23, 2021.

Viberzi™ (eluxadoline) [prescribing information]. Parsippany, NJ: Allergan, Inc; June 2020.  
[https://www.allergan.com/assets/pdf/viberzi\\_pi](https://www.allergan.com/assets/pdf/viberzi_pi) Accessed July 23, 2021.

Vibramycin® (doxycycline) [prescribing information]. Collegeville, PA: Pfizer Laboratories Div Pfizer Inc; December 2019.  
<http://labeling.pfizer.com/ShowLabeling.aspx?format=PDF&id=611> Accessed July 23, 2021.

Viibryd® (vilazodone hydrochloride) [prescribing information]. Parsippany, NJ: Allergan, Inc; January 2020.  
[https://www.allergan.com/assets/pdf/viibryd\\_pi](https://www.allergan.com/assets/pdf/viibryd_pi) Accessed July 23, 2021.

Viokace® (pancrelipase) [prescribing information]. Irvine, CA: Allergan USA, Inc. March 2020. Available at:  
[https://www.allergan.com/assets/pdf/viokace\\_pi](https://www.allergan.com/assets/pdf/viokace_pi). Accessed July 23, 2021.

Vivlodex™ (meloxicam) [prescribing information]. Wayne, PA: Egalet US Inc. April 2019. Available from:  
<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=11771dcf-0803-4de9-a2fe-73edec256209&type=display>. Accessed July 23, 2021.

Vraylar™ (cariprazine) [prescribing information]. Parsippany, NJ: Allergan USA, Inc. May 2019.  
[https://www.allergan.com/assets/pdf/vraylar\\_pi](https://www.allergan.com/assets/pdf/vraylar_pi) Accessed July 23, 2021.

Vusion® (miconazole nitrate, zinc oxide, white petrolatum) [prescribing information]. Newtown, PA: Prestium Pharma, Inc.; May 2018. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/021026s013lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021026s013lbl.pdf). Accessed July 23, 2021.

Vytorin® (ezetimibe and simvastatin) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; October 2019. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/021687s062lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021687s062lbl.pdf). Accessed July 23, 2021.

Vyzulta™ (latanoprostene bunod) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. May 2019.  
<https://www.bausch.com/Portals/69/-/m/BL/United%20States/USFiles/Package%20Inserts/Pharma/vyzulta-prescribing-information.pdf> Accessed July 23, 2021.

Wellbutrin XL® (bupropion hydrochloride) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; February 2020. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021515s036lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021515s036lbl.pdf) Accessed. July 23, 2021.

Xanax® (alprazolam) [prescribing information]. Kalamazoo, MI: Pharmacia and Upjohn Company LLC; 2017. <http://labeling.pfizer.com/ShowLabeling.aspx?id=547> Accessed July 23, 2021.

Xcopri® (cenobamate) [prescribing information]. Paramus, NJ: SK Life Science, Inc.; August 2020. Available from: [www.xcopri.com/wp-content/uploads/2020/04/PI-and-Med-Guide.pdf](http://www.xcopri.com/wp-content/uploads/2020/04/PI-and-Med-Guide.pdf). Accessed July 23, 2021.

Xelpros® (latanoprost) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc. December 2020. Available at: <https://xelpros.com/pdf/XelprosPI.pdf>. Accessed July 23, 2021.

Xepi™ (ozenoxacin) [prescribing information]. Wayne, PA. Cutanea Life Sciences, Inc. January 2020. Available at: <https://www.xepicream.com/resources/full-prescribing-information>. Accessed July 23, 2021.

Ximino® (minocycline hydrochloride extended release) [package insert]. Jacksonville, FL: Ranbaxy Laboratories Inc; November 2020. <http://www.ximinorx.com/pdf/ximino-er-caps-full-prescribing-information.pdf> Accessed July 23, 2021.

Xolegel® (ketoconazole) [prescribing information]. West Chester, PA: Aqua Pharmaceuticals; 2015. Accessed July 23, 2021.

Xopenex® (levalbuterol) [prescribing information]. Lake Forest, IL: Akorn, Inc.; 2015. Accessed July 23, 2021.

Xultophy® (insulin degludec and liraglutide) [prescribing information]. Plainsboro, NJ: Novo Nordisk; November 2019. <https://www.novo-pi.com/xultophy10036.pdf> Accessed July 23, 2021.

Yupelri™ (revenfenacin) [prescribing information]. Morgantown, WV: Mylan Specialty L.P. May 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6dfebf04-7c90-436a-9b16-750d3c1ee0a6&type=display>. Accessed July 23, 2021.

Zanaflex® (tizanidine hydrochloride) [prescribing information]. Ardsley, NY: Acorda Therapeutics, Inc.; 2017. Accessed July 23, 2021.

Zelnorm™ (tegaserod) [prescribing information]. Germany: Sloan Pharma. July 2019. Available from: [https://www.myzelnorm.com/assets/pdfs/PM-000413\\_ZELNORM\\_PI-MG\\_160x850mm\\_v6FNL\\_ND.pdf](https://www.myzelnorm.com/assets/pdfs/PM-000413_ZELNORM_PI-MG_160x850mm_v6FNL_ND.pdf). Accessed July 23, 2021.

Zerviate™ (cetirizine ophthalmic solution) [prescribing information]. Forth Worth, TX: Eyevance Pharmaceuticals, LLC.; February 2020. Available from: [https://myzerviate.com/files/Zerviate\\_PI.pdf](https://myzerviate.com/files/Zerviate_PI.pdf). Accessed July 23, 2021.

Zestril® (lisinopril) [prescribing information], Wilmington, DE; July 2017. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/019777s076lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019777s076lbl.pdf). Accessed July 23, 2021.

Zetia® (ezetimibe) [prescribing information]. Whitehouse Station, NJ: Merck & Co., INC; August 2013. [https://www.merck.com/product/usa/pi\\_circulars/z/zetia/zetia\\_pi.pdf](https://www.merck.com/product/usa/pi_circulars/z/zetia/zetia_pi.pdf). Accessed July 23, 2021.

Zilxi™ (minocycline) [prescribing information]. Bridgewater, NJ: Foamix Pharmaceuticals Inc.; May 2020. Available from: <https://www.zilxihcp.com/downloads/zilxi-prescribing-information.pdf>. Accessed July 23, 2021.

Zioptan® (tafluprost) [prescribing information]. Lake Forest, IL: Akorn, Inc.; November 2018. [http://www.akorn.com/documents/catalog/package\\_inserts/17478-609-30.pdf](http://www.akorn.com/documents/catalog/package_inserts/17478-609-30.pdf) Accessed July 23, 2021.

Zipsor® (diclofenac) [prescribing information]. Newark, CA: Depomed, Inc.; May 2016. Available from: <https://www.zipsor.com/pdf/prescribing-information.pdf>. Accessed July 23, 2021.

Ztlido™ (lidocaine topical system) [prescribing information]. San Diego, CA. Scilex Pharmaceuticals Inc. November 2018. Available at: <https://www.ztlido.com/sites/default/files/pdfs/ZTlido-LABEL.pdf>. Accessed July 23, 2021.

Zmax® (azithromycin dehydrate) [prescribing information]. Collegeville, PA: Pfizer Laboratories Div Pfizer Inc; 2017. Accessed July 23, 2021.

Zocor® (simvastatin) [prescribing information]. Jersey City, NJ: Organon & Co.; June 2021. Available from: [https://www.organon.com/product/usa/pi\\_circulars/z/zocor/zocor\\_pi.pdf](https://www.organon.com/product/usa/pi_circulars/z/zocor/zocor_pi.pdf). Accessed July 23, 2021.

Zyflo CR® (zileuton) [prescribing information]. Cary, NC: Chiesi USA, Inc.; December 2018. Available from: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/022052s014lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022052s014lbl.pdf). Accessed July 23, 2021.

Zypitamag® (pitavastatin) [prescribing information]. Pennington, NJ: Zydus Pharmaceuticals. June 2020. Available from: [https://www.zypitamag.com/docs/prescribing\\_information.pdf?v=20200827075654](https://www.zypitamag.com/docs/prescribing_information.pdf?v=20200827075654). Accessed July 23, 2021.

Zoloft® (sertraline hydrochloride) [prescribing information]. Belmont, WA: Roerig; April 2019. <http://labeling.pfizer.com/ShowLabeling.aspx?id=517#page=1> Accessed July 23, 2021.

Zorvolex® (diclofenac) [prescribing information]. Wayne, PA: Egalet US Inc. September 2019. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f83d5c03-8094-4216-8969-a1102da68f15&type=display>. Accessed July 23, 2021.

Micromedex. Available at <http://www.micromedexsolutions.com/>. Accessed July 23, 2021.

Cialis (tadalafil) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; Feb 2018. Available from: <https://pi.lilly.com/us/cialis-pi.pdf>. Accessed July 23, 2021.

Levitra (vardenafil) [prescribing information]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc; August 2017. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a01def95-c0ef-43b9-bd9e-5565b2385ad3&type=display>. Accessed July 23, 2021.

Staxyn (vardenafil) [prescribing information]. Research Triangle Park, NC. Glaxo Smith Kline. August 2017. Available from: <http://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Brands/STAXYN/> Accessed July 23, 2021

Stendra (avanafil) [prescribing information]. Mopuntain View, CA. Vivus, Inc; August 2018. Available from: <https://www.stendra.com/wp-content/documents/Stendra-PI-Mist.pdf>. Accessed July 23, 2021

Viagra (sildenafil) [prescribing information]. New York, NY: Pfizer Labs; December 2017. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=0b0be196-0c62-461c-94f4-9a35339b4501&type=display>. Accessed July 23, 2021

Winlevi (clascoterone) [prescribing information]. Cassiopea, Inc; August 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/213433s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213433s000lbl.pdf). Accessed July 23, 2021.

Qdolo (tramadol hydrochloride) [prescribing information]. Athena Bioscience, LLC. September 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2020/214044Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214044Orig1s000ltr.pdf). Accessed July 23, 2021.

Oxaydo (oxycodone HCl) [prescribing information]. Egalet US Inc. December 2016. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/202080s005s006lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202080s005s006lbl.pdf). Accessed July 23, 2021.

Wynzora (calcipotriene and betamethasone dipropionate) [prescribing information]. MC2 Therapeutics, Inc. July 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/213422s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213422s000lbl.pdf). Accessed July 23, 2021

Sutab (sodium sulfate, magnesium sulfate, and potassium chloride) [prescribing information]. Braintree Laboratories, Inc. November 2020. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/213135s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213135s000lbl.pdf). Accessed July 23, 2021.

Impeklo (clobetasol propionate) [prescribing information]. Mylan Specialty LP. May 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/213691s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213691s000lbl.pdf). Accessed July 23, 2021.

Alkindi (hydrocortisone) [prescribing information]. Eton Pharmaceuticals, Inc. September 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/213876s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213876s000lbl.pdf). Accessed July 23, 2021.

Ongnetys (opicapone) [prescribing information]. Neurocrine Biosciences, Inc. April 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/212489s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212489s000lbl.pdf). Accessed July 23, 2021.

Tecfidera (dimethyl fumarate) [prescribing information]. Biogen Idec Inc. March 2013. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/204063lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204063lbl.pdf). Accessed July 23, 2021.

Intrarosa (prasterone) [prescribing information]. Endoceutics Inc. November 2016. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/208470s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208470s000lbl.pdf). Accessed July 23, 2021.

Femring (estradiol acetate vaginal ring) [prescribing information]. Warner Chilcott Inc. May 2009. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/021367s009lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021367s009lbl.pdf). Accessed July 23, 2021.

Vagifem (estradiol vaginal tablets) [prescribing information]. Novo Nordisk Inc. November 2009. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020908s013lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020908s013lbl.pdf). Accessed July 23, 2021.

Estrace cream [prescribing information]. Warner Chilcott Inc. April 2005. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2005/86069s018lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/86069s018lbl.pdf). Accessed July 23, 2021.

Orphenadrine [prescribing information]. 3M Pharmaceuticals. October 2006. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2007/012157s028lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/012157s028lbl.pdf). Accessed July 23, 2021.

Vesicare/Vesicare LS (solifenacin succinate) [prescribing information]. Astellas Pharma Technologies, Inc. June 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/021518s016lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021518s016lbl.pdf). Accessed July 23, 2021.

Trileptal (oxcarbazepine) [prescribing information]. Novartis Pharmaceuticals Corporation. March 2017. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/021014s036lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021014s036lbl.pdf). Accessed July 23, 2021.

Ongentys (opicapone) [prescribing information]. San Diego, CA: Neurocrine Biosciences. April 2020. Available at: <https://www.neurocrine.com/assets/ONGENTYS-PI.pdf>. Accessed July 23, 2021.

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Refer to table above

**Cross References:**

Rx.01.33 Off-Label Use

Rx.01.76 Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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