WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 6/1/24 – 6/30/24

FDA Drug Safety Communications & Drug Information Updates:

Safety Risks Associated with Sulfite-Containing Compounded Drugs 6/5/24

The FDA alerted health care professionals, compounders, and patients about the risk of potentially serious allergic-type reactions to sulfite containing compounded drugs following receipt of reports of reactions. The FDA encouraged compounders to indicate the presence of sulfites on product labels or including a sulfite warning statement, and encouraged patients and health care professionals to ask compounders about the presence of sulfites when there are concerns about sulfite allergies or sensitivities. Examples of sulfites include sodium bisulfite, sodium metabisulfite, sodium sulfite, potassium bisulfite, and potassium metabisulfite. Allergic reaction reports have included complaints of conjunctivitis, itchy eyes, swollen eyelids, and respiratory failure.

REMS for CAR-T Immunotherapies Modified to Minimize Burden on Healthcare Delivery Systems 6/26/24

The FDA modified the Risk Evaluation and Mitigation Strategy (REMS) for the BCMA- or CD19-directed autologous chimeric antigen receptor (CAR) T cell immunotherapies to minimize the burden of compliance. Requirements for educational and training materials have been removed from the REMS, as the current labeling and Medication Guide conveys the risks adequately. In addition, the requirement to report adverse events suggestive of cytokine release syndrome and neurologic toxicities has been removed, as standard postmarketing adverse event monitoring has been deemed sufficient for routine safety monitoring. A minimum of two doses of tocilizumab must still be available on site for each patient before infusion of the CAR T-cell immunotherapy.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

Homeopathic StellaLife Oral Care Spray Unflavored and Advanced Formula Peppermint Oral Care Rinse by HomeoCare Laboratories: Recall – Microbial Contamination 6/6/24

Homeocare Laboratories recalled two batches of homeopathic StellaLife Oral Care Products manufactured in 2024 due to FDA findings of microbial contamination. The 2 products were found to contain higher than acceptable levels of TAMC (found in StellaLife Advanced Formula Peppermint Vega Oral Care Rinse) and *Bacillus* spp. (found in StellaLife Vega Oral Spray, Unflavored).

Suntegrity Impeccable Skin Sunscreen Foundation (Multiple Shades) by Suntegrity Skincare: Recall – Microbial Contamination 6/13/24

Suntegrity Skincare recalled nine lots of Suntegrity Impeccable Skin Sunscreen Foundation (Multiple Shades) based on the discovery of a higher than acceptable microbiological mold count (Species: *Aspergillus sydowii*) in some tubes of Lot 115BU that developed post-release and over time in a recent test. As a precaution, Lots 107IV, 107NU, 109NU, 117BU, 113SA, 114SA, 106BR, and 101MO are also being recalled despite clear test results.

Potassium Chloride ER Capsules USP, 10 mEq, Glenmark Pharmaceuticals: Recall – Failed Dissolution 6/25/24

Glenmark Pharmaceuticals recalled 114 batches of Potassium Chloride Extended-Release Capsules USP, (750 mg) 10 mEq because of failed dissolution. Affected lot numbers and expiration dates can be found on the FDA web site.

Potassium Chloride ER Capsules USP, 10 mEq, American Health Packaging: Recall – Failed Dissolution 6/25/24

American Health Packaging, on behalf of BluePoint Laboratories, recalled 21 batches of Potassium Chloride Extended-Release Capsules USP, (750 mg) 10 mEq because of failed dissolution. Affected lot numbers and expiration dates can be found on the FDA web site.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
Diamond Shruumz Infused Cones, Chocolate Bars, and Gummies (Micro- and Mega/Extreme-Dose), Diamond Shruumz Products*	Recreational drug	Contains Muscimol, a natural high-risk chemical that can cause severe CNS and GI issues (seizures, vomiting, loss of consciousness). Longer list of AE here.
Infla-650	Pain	Acetaminophen, diclofenac, and phenylbutazone[1]
La Paix	Sexual enhancement	Sildenafil
Nature's Wonderland Thyroid Formulary, Penn Herb Company Ltd*	Support of healthy thyroid function	Salmonella contamination
Ram It & To The Moon capsules, Integrity Products*	Sexual enhancement	Sildenafil and tadalafil
Umary	Pain	Diclofenac and omeprazole

*recalled

[1]phenylbutazone is an NSAID discontinued for human use in the U.S. due to the risk of serious and life-threatening adverse events including aplastic anemia

New Product Shortages	***Date Initially Posted***
Vitamin A Palmitate Injection	6/10/24

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Caspofungin injection 70 mg (Cancidas, Merck Sharp & Dohme); generics remain available	6/27/24
Triazolam tablet 0.25 mg (Halcion, Pfizer); generics remain available	6/27/24

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Imetelstat sodium / Rytelo / Geron Corporation	Oligonucleotide telomerase inhibitor for the treatment of adult patients with myelodysplastic syndromes meeting the following criteria: low to intermediate risk, transfusion dependent anemia that requires 4+ red blood cell units within 8 weeks and are non-responsive to or ineligible for erythropoiesis-stimulating agents	6/6/24
Elafibranor / Iqirvo / Ipsen Biopharmaceuticals	Peroxisome proliferator-activated receptor agonist for the treatment of primary biliary cholangitis	6/10/24
Pneumococcal 21-valent conjugate vaccine / Capvaxive / Merck	Pneumococcal vaccine for active immunization for prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8 ,9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F and 35B, and for prevention of pneumonia caused by 21 of these serotypes in individuals 18 years of age and older	6/17/24
Sofpironium / Sofdra / Botanix SB	Anticholinergic for the treatment of primary axillary hyperhidrosis in adults and children 9 years of age and older	6/18/24
Crovalimab-akkz / Piasky / Genentech	Complement C5 inhibitor for the treatment paroxysmal nocturnal hemoglobinuria in adults and pediatric patients 13 years and older and weighing at least 40 kg	6/20/24
Ensifentrine / Ohtuvayre / Verona Pharma	Phosphodiesterase (PDE)3 and PDE4 inhibitor for maintenance treatment of chronic obstructive pulmonary disease	6/26/24

New Indications:	***Description***	***Date Approved***
Lacosamide / Motpoly XR / Aucta Pharmaceuticals Inc	Treatment of primary generalized tonic-clonic seizures in adults and children weighing at least 50 kg	6/7/24
Respiratory Syncytial Virus Vaccine, Adjuvanted / Arexvy / GlaxoSmithKline Biologicals	Indication expanded to include use in individuals 50 through 59 years of age who are increased risk for lower respiratory tract disease caused by respiratory syncytial virus	6/7/24
Dapagliflozin / Farxiga / AstraZeneca Pharmaceuticals LP	Indication expanded to include use in children 10 years and older for adjunctive treatment to improve glycemic control in type 2 diabetes mellitus.	6/12/24
Dapagliflozin and metformin hydrochloride / Xigduo XR / AstraZeneca Pharmaceuticals LP	Indication expanded to include use in children 10 years and older for adjunctive treatment to improve glycemic control in type 2 diabetes mellitus.	6/12/24
Repotrectinib / Augtyro / Bristol-Myers Squibb Company	Accelerated approval for treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and that have progressed following treatment or have no satisfactory alternative therapy	6/13/24
Blinatumomab / Blincyto / Amgen	Treatment of CD19+ Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia in the consolidation phase of multiphase chemotherapy in adults and children 1 month and older	6/14/24
Durvalumab / Imfinzi / AstraZeneca	In combination with carboplatin and paclitaxel followed by durvalumab as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient	6/14/24
Pembrolizumab / Keytruda / Merck Sharp & Dohme	In combination with carboplatin and paclitaxel, followed by pembrolizumab as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma	6/17/24
Risankizumab-rzaa/ Skyrizi / AbbVie Inc.	Treatment of moderately to severely active ulcerative colitis in adults	6/18/24
Delandistrogene moxeparvovec-rokl / Elevidys / Sarepta Therapeutics	Indication expended to include individuals at least 4 years of age with Duchenne muscular dystrophy who are ambulatory or non-ambulatory and have a confirmed mutation in the DMD gene	6/20/24
Adagrasib / Krazati / Mirati Therapeutics Inc.	In combination with cetuximab in adults with KRAS G12C-mutated locally advanced or metastatic colorectal cancer who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy	6/21/24
Efgartigimod alfa & hyaluronidase-qvfc / Vyvgart Hytrulo / Argenx BV	Approved for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.	6/21/24
Pitolisant / Wakix / Harmony Biosciences	Indication expanded to include treatment of excessive daytime sleepiness in pediatric patients 6 years of age and older with narcolepsy	6/21/24
Epcoritamab-bysp / Epkinly / Genmab US, Inc.	For the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy	6/26/24

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Tralokinumab-ldrm / Adbry / Leo Pharma Inc	Autoinjector: 300 mg/2 mL; single-dose autoinjector for use in adults as an alternative to two 150 mg injections using a prefilled syringe	6/12/24
Immune globulin intravenous, human-dira / Yimmugo / Kedtrion	Intravenous solution: 10%, 5 g in 50 mL, 10 g in 100 mg, and 20 g in 200 mL; for the treatment of primary humoral immunodeficiency in patients 2 years and older	6/13/24
Vigabatrin / Vigafyde / Pyros Pharmaceuticals	Oral solution: 100 mg/mL; for the monotherapy treatment of infantile spasms in patients 1 month to 2 years of age for whom the potential benefit outweighs the potential risk of vision loss	6/17/24
Thiotepa / TepyLute / Shorla Pharma Ltd	Injection: 15 mg/1.5 mL; for intravenous administration in the treatment of adenocarcinoma of the breast or ovary	6/25/24
Tadalafil / Chewtadzy / ANI Pharmaceuticals	Chewable tablets: 5 mg, 10 mg, 20 mg; for the treatment of erectile dysfunction and/or benign prostatic hyperplasia	6/28/24

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Imeltelstat / Rytelo / Geron Corporation	
Generic Name / Brand Name / Company	Imeltelstat / Rytelo / Geron Corporation
Date of approval	6/6/24
Drug Class (Mechanism of Action if novel agent)	Oligonucleotide human telomerase inhibitor; prevents telomere binding leading to reduction of telomere length, reduction of malignant stem and progenitor cell proliferation, and apoptosis
Indication	Treatment of adult patients with low to intermediate-1 risk myelodysplastic syndromes with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents
Comparative agent – Therapeutic interchange?	Luspatercept (Reblozyl)
Dosage forms/strengths.	Injection: 47 mg and 188 mg powder for reconstitution
Common Dose/sig	7.1 mg/kg as an IV infusion over 2 hours every 4 weeks
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Rythmol
Clinical Use Evaluation	
Common Adverse Effects	≥10%: decreased platelets, white blood cells, neutrophils; increased AST, alkaline phosphatase, ALT; fatigue, prolonged partial thromboplastin time, arthralgia/myalgia, headache
Severe Adverse Effects	Thrombocytopenia, neutropenia, infusion reactions, hypertensive crisis
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	CBC with platelets and LFTs prior to administration, weekly for the first 2 cycles, prior to each cycle thereafter, and as clinically indicated.
Used in Pediatric Areas	Safety and effectiveness have not been established
Renal or Hepatic Dosing	No dosage adjustments in mild to moderate renal or hepatic impairment; not studied in severe renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No labeled contraindications. Can cause severe thrombocytopenia, neutropenia, infusion-related reactions; monitor closely. May cause embryo fetal harm when administered to pregnant woman. Discontinue treatment if a patient does not experience a decrease in RBC transfusion burden after 24 weeks of treatment.
Special administration technique or considerations	Premedicate at least 30 minutes prior to dosing with diphenhydramine (or equivalent) 25 mg to 50 mg IV or orally and hydrocortisone (or equivalent) 100 mg to 200 mg IV or orally. Infuse over 2 hours. Monitor patients for at least one hour after the infusion. Dose modifications are advised for Grade 3 and Grade 4 adverse reactions.
Prepared by	Lynda Ogbuji
Source	Rytelo (imetelstat) [prescribing information]. Geron Corporation: Foster City, CA; June 2024.

Elafibranor / Iqirvo / Ipsen Biopharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Elafibranor / Iqirvo / Ipsen Biopharmaceuticals, Inc.
Date of approval	6/10/24
Drug Class (Mechanism of Action if novel agent)	Peroxisome proliferator-activated receptor (PPAR) agonist; inhibits bile acid synthesis
Indication	Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Tablets: 80 mg
Common Dose/sig	Take 80 mg by mouth once daily with or without food.
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Fiber-n-more, Iquix
Clinical Use Evaluation	
Common Adverse Effects	≥5%: weight gain, diarrhea, abdominal pain, nausea, vomiting, arthralgia, constipation, muscle pain, fracture, gastroesophageal reflux disease, dry mouth, weight loss, rash
Severe Adverse Effects	Rhabdomyolysis, acute kidney injury, fractures, drug-induced liver injury, hypersensitivity reactions
Severe Drug-Drug Interactions	Hormonal contraceptives (use alternative or additional non-hormonal contraceptive), HMG-CoA reductase inhibitors (monitor for muscle injury), rifampin (monitor for elafibranor response), bile acid sequestrants (separate administration).
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy testing. Obtain clinical and laboratory liver assessments (ALT, AST, TB, and/or alkaline phosphatase [ALP]) at treatment initiation and monitor thereafter.
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustments in mild, moderate, or severe renal impairment, or mild hepatic impairment. Consider discontinuing if moderate or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Avoid use of this medication in patients with complete biliary obstruction. Use is not recommended in patients with decompensated cirrhosis (eg, ascites, variceal bleeding, hepatic encephalopathy). Assess for myalgia and myopathy before starting. Risks of myalgia, myopathy, rhabdomyolysis, fractures, fetal harm, drug-induced liver injury, and hypersensitivity reactions.
Special administration technique or considerations	May take with or without food. Take at least 4 hours before or 4 hours after administering a bile acid sequestrant, or as great an interval as possible.
Prepared by	Ashlin Parsons
Source	Iqirvo (elafibranor) [prescribing information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.

Pneumococcal 21-valent Conjugate Vaccine / Capvaxive / Merck Sharp & Dohme LLC	
Generic Name / Brand Name / Company	Pneumococcal 21-valent Conjugate Vaccine / Capvaxive / Merck Sharp & Dohme LLC
Date of approval	6/17/24
Drug Class (Mechanism of Action if novel agent)	Vaccine; induces immune response against 22 *S. pneumoniae* serotypes.
Indication	Active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B and pneumoniae caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and younger.
Comparative agent – Therapeutic interchange?	PREVNAR 20, Pneumovax 23
Dosage forms/strengths.	Injection: single-dose prefilled Luer Lock syringe 0.5 ml
Common Dose/sig	Administer single dose of 0.5 ml intramuscularly in the deltoid
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Pneumococcal conjugate vaccine, capivasertib, Caplyta
Clinical Use Evaluation	
Common Adverse Effects	>10%: injection site pain, fatigue, headache, myalgia, injection site erythema, injection site swelling
Severe Adverse Effects	Anaphylaxis
Severe Drug-Drug Interactions	None
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Do not administer to individuals with history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or to diphtheria toxoid. Individuals who are immunosuppressed or immunocompromised may have a reduced immune response to the vaccine.
Special administration technique or considerations	Administer intramuscularly. Medical treatment must be immediately available to manage potential anaphylactic reactions.
Prepared by	Lynda Ogbuji
Source	Capvaxive (Pneumococcal 21-Valent Conjugate Vaccine) [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; June 2024.

Sofpironium / Sofdra / Botanix SB Inc.	
Generic Name / Brand Name / Company	Sofpironium / Sofdra / Botanix SB Inc.
Date of approval	6/18/24
Drug Class (Mechanism of Action if novel agent)	Anticholinergic
Indication	Treatment of primary axillary hyperhidrosis
Comparative agent – Therapeutic interchange?	Glycopyrronium topical
Dosage forms/strengths.	Topical gel: 12.45% in a 50 mL bottle
Common Dose/sig	Apply 1 pump of gel per underarm once daily at bedtime
DEA Schedule	None
Date of market availability	4th quarter 2024
Similar Medication Names	Glycopyrronium
Clinical Use Evaluation	
Common Adverse Effects	>2%: dry mouth, blurred vision, application site pain, application site erythema, mydriasis, application site dermatitis, application site pruritus, urinary retention, application site irritation
Severe Adverse Effects	Urinary retention, heat illness (due to decreased sweating)
Severe Drug-Drug Interactions	Anticholinergic medications: additive effects; avoid coadministration CYP2D6 strong inhibitors: avoid coadministration
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Indicated in patients 9 years and older; efficacy and safety not established in patients younger than 9 years
Renal or Hepatic Dosing	No dosage adjustment; has not been assessed in renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: conditions exacerbated by anticholinergic effects Warnings: urinary retention, control of body temperature, blurred vision – avoid operating machinery or an automobile if blurred vision
Special administration technique or considerations	Do not apply within 8 hours of shaving armpits or 30 minutes of showering. Wash hands immediately after applying.
Prepared by	Terri Levien
Source	Sofdra (sofpironium) [prescribing information]. Wayne, PA: Botanix SB Inc.; June 2024

Crovalimab-akkz / PiaSky / Genentech	
Generic Name / Brand Name / Company	Crovalimab-akkz / PiaSky / Genentech
Date of approval	6/20/24
Drug Class (Mechanism of Action if novel agent)	Complement C5 inhibitor
Indication	Treatment of paroxysmal nocturnal hemoglobinuria
Comparative agent – Therapeutic interchange?	Eculizumab, Ravulizumab
Dosage forms/strengths.	Injection: 340 mg/2 mL in single dose vial
Common Dose/sig	Weight based loading dose: 1,000 mg IV on day 1 if 40 kg to ≤ 100 kg and 1,500 mg IV if >100 kg; followed by 340 mg subcutaneously on days 2, 8, 15, and 22 (for all patients with weight ≥ 40 kg). Maintenance dose 680 mg subcutaneously if 40 kg to ≤ 100 kg and 1,020 mg if weight > 100 kg, administered subcutaneously every 4 weeks
DEA Schedule	None
Date of market availability	Available under a REMS
Similar Medication Names	Crofab, Crotalidae Immune Fab
Clinical Use Evaluation	
Common Adverse Effects	≥10%: infusion-related reaction, respiratory tract infection, viral infection, Type III hypersensitivity reactions
Severe Adverse Effects	Meningococcal infections, infusion-related reactions
Severe Drug-Drug Interactions	Monitor closely when patients are switched from another C5 inhibitor
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Hemoglobin, lactate dehydrogenase
Used in Pediatric Areas	Indicated for use patients 13 years and older and weighing at least 40 kg; efficacy and safety not established in patients less than 13 years of age
Renal or Hepatic Dosing	No dosing adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: initiation during unresolved serious Neisseria meningitis infection and serious hypersensitivity to any ingredients Boxed warning: increased risk of serious and life-threatening infections caused by N. meningitidis; complete meningococcal vaccination at least 2 weeks prior to the first dose Warnings: • Monitor patients switching from another C5 inhibitor due to risk of type III hypersensitivity reactions • Increased susceptibility to infections caused by encapsulated bacteria • Monitor for infusion- and injection-related reactions
Special administration technique or considerations	First loading dose administered by IV infusion over 60 minutes or 90 minutes, diluted in 0.9% sodium chloride injection, with use of a 0.2 micron in-line filter and flush following infusion. The IV loading dose is followed by 4 additional subcutaneous loading doses. Maintenance dose is administered every 4 weeks by subcutaneous injection. Each subcutaneous injection is 2 mL; a 680 mg dose is achieved with two 340 mg subcutaneous injections and the 1020 mg dose is achieved with three consecutive 340 mg subcutaneous injections.
Prepared by	Terri Levien
Source	PiaSky (crovalimab-akkz) [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2024.

Ensifentrine / Ohtuvayre / Verona Pharma	
Generic Name / Brand Name / Company	Ensifentrine / Ohtuvayre / Verona Pharma
Date of approval	6/26/24
Drug Class (Mechanism of Action if novel agent)	Phosphodiesterase 3 (PDE3) and PDE4 inhibitor
Indication	Maintenance treatment of chronic obstructive pulmonary disease
Comparative agent – Therapeutic interchange?	Roflumilast oral (PDE4 inhibitor)
Dosage forms/strengths.	Inhalation suspension: 3 mg/2.5 mL in unit-dose ampules
Common Dose/sig	3 mg twice daily administered by oral inhalation using a nebulizer
DEA Schedule	None
Date of market availability	3rd quarter 2024
Similar Medication Names	-
Clinical Use Evaluation	
Common Adverse Effects	>1%: back pain, hypertension, urinary tract infection, diarrhea
Severe Adverse Effects	Suicidality
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments in renal impairment; caution in patients with hepatic impairment due to increased exposure.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: hypersensitivity to any product components. Warnings: • not for treatment of acute symptoms • discontinue if paradoxical bronchospasm occurs • increased risk of psychiatric adverse reactions, including suicidality
Special administration technique or considerations	Administer using a standard jet nebulizer with a mouthpiece. Shake ampules vigorously immediately before use
Prepared by	Terri Levien
Source	Ohtuvayre (ensifentrine) [prescribing information]. Raleigh, NC: Verona Pharma, Inc.; June 2024.