College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 10/1/19 – 10/31/19

FDA Drug Safety Communications & Drug Information Updates:

FDA Report on Root Causes and Potential Solutions to Drug Shortages 10/30/19
The FDA released a report from the inter-agency Drug Shortages Task Force to address root causes and potential solutions for drug shortages. While there was no easy solution to the problems identified and no single cause for drug shortages, the task force offers three recommendations to address the root causes of shortages. The recommendations included taking steps to increase understanding of the impact of drug shortages and companies' contracting practices, support ideas incentivizing manufacturers focus on continuous improvement and early detection of supply chain issues, and consider new contracting approaches to ensure a reliable supply of drugs.

Ranitidine Updates – N-Nitrosodimethylamine (NDMA) Oct. 2019
The FDA is maintaining a site with updates and press announcements on NDMA testing in ranitidine products and ranitidine recalls, as well as a Questions and Answers page regarding the NDMA impurities.

Rompe Pecho cough syrups by Efficient Laboratories: Avoid Use – Microbial Contamination 10/11/19
The FDA advised consumers not to use Rompe Pecho EX and Rompe Pecho CF cough syrups distributed by Efficient Laboratories, Inc., Miami, Florida, due to microbial contamination. The company has not initiated an FDA recommended recall.

Antihemophilic Factor/von Willebrand Factor Complex, Human (Humate-P) by CSL Behring: Error in Packaging 10/15/19
CSL Behring issued a notification regarding a packaging error on the folding box of Humate-P for lots of all fill sizes (600, 1200, 2400 IUs) distributed since February 2019. An error during packaging led to potency data being shifted downwards which could lead to confusion when reading the von Willebrand Factor and Factor VIII potency. The correct values are printed correctly on the product vials and these values should be used for dosage calculations.

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

Plum and Sapphirine Microbore Infusion Sets with Inline Filters by ICU Medical: Recall - Leakage 10/8/19
ICU Medical recalled lots of Plum and Sapphire Microbore Infusion Sets with inline filters due to the potential for small amounts of fluid to leak out of the air vents on the inline filters. The complete list of recalled item codes and lot numbers can be found on an announcement on the FDA site.

Sterile Compounded Drug Products by Innoveix Pharmaceuticals, Inc.: Recall – Lack of Sterility Assurance 10/10/19
Innoveix Pharmaceuticals, Inc. recalled all sterile compounded drug products to the consumer level due to concerns arising following a routine inspection of the pharmacy by the FDA. The affected products are injectable Human Chorionic Gonadotropin (HCG) and injectable Sermorelin w/GHRP2.

Sterile Injectable Vials of Products by Viatrexx Bio Inc.: Recall – Lack of Sterility Assurance 10/15/19
Viatrexx Bio Inc. Newark, Delaware, recalled 10 mL injectable vials of products intended to be sterile, due to a lack of sterility assurance. The full list of products can be found on the FDA site.

Ranitidine by Perrigo: Recall – Possible Presence of NDMA 10/23/19
Perrigo Company recalled to the customer level all ranitidine products due to possible presence of NDMA.

Ranitidine (Zantac OTC) by Sanofi: Recall – Possible Presence of NDMA 10/23/19
As a precautionary measure, Sanofi recalled all Zantac OTC products including Zantac 150, Zantac 150 Cool Mint, and Zantac 75 following FDA announcement that some ranitidine products could contain NDMA at low levels and asked manufacturers to conduct testing.

Ranitidine by Dr. Reddy's: Recall – Possible Presence of NDMA 10/23/19
Dr. Reddy's Laboratories Ltd. recalled all of its ranitidine medications sold in the U.S. due to confirmed contamination with NDMA above levels established by the FDA. The recall includes prescription and over-the-counter products marketed under Dr. Reddy's, Sam's Club, Walgreens, Walmart, Kroger, CVS, CDMA, HCA, Target, Thirty Madison, and GeriCare labels.

Ranitidine Capsules by Novitium Pharma LLC: Recall – Possible Presence of NDMA 10/25/19
Novitium Pharma LLC recalled all unexpired quantities and lots of ranitidine hydrochloride 150 mg and 300 mg capsules to the consumer level due to elevated levels of NMDA. The recalled NDCs are 70954-001-20, 70954-001-40, 70954-002-10, and 70954-002-40.

Ranitidine Oral Solution by Lannett Company, Inc.: Recall – Due to Presence of NDMA 10/25/19
Lannett Company, Inc. recalled all lots of Ranitidine Syrup 15 mg/mL (Ranitidine Oral Solution, USP; NDC 54838-550-80) to the consumer level due to elevated levels of NMDA.

Alprazolam Tablets by Mylan Pharmaceuticals: Recall – Potential presence of foreign substance 10/28/19
Mylan Pharmaceuticals recalled of one lot (lot # 8082708, exp. Sept. 2020) of alprazolam 0.5 mg tablets in bottles of 500 to the consumer level due to the potential presence of foreign substance.

Lactated Ringer's Injection USP and 0.9% Sodium Chloride Injection USP: Recall – Presence of Particulate Matter 10/30/19
ICU Medical voluntarily recalled to the hospital level one lot of Lactated Ringer's Injection (Lot: 84-603-FW) and one lot of 0.9% Sodium Chloride injection (Lot: 95-101-C6) due to the presence of particulate matter.

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***
CHU Dietary Supplement Product	Sexual enhancement	Sildenafil and tadalafil
CholesLo	Lowering cholesterol	Lovastatin
Green Lumber	Sexual enhancement	Tadalafil
Skinny Pill	Weight loss	"geranium extract" – 1,3-dimethylamylamine or methylhexanamine (DMAA)[1]

[1]DMAA ingestion can elevate blood pressure

New Product Shortages	***Date Initially Posted***
Nalbuphine HCl Injection	10/11/19
Vincristine Sulfate Injection, USP (Preservative-Free) –	10/16/19
Atropine Sulfate Ophthalmic Ointment	10/18/19
Bacitracin Ophthalmic Ointment – 3.5 g (NDC 0574-4022-35)	10/23/19
Trifluridine 1% - Ophthalmic Solution	10/29/19
Anagrelide HCl Capsules	10/29/19

Product Discontinuations/Withdrawals	***Date Posted***
Tolterodine tartrate extended release capsules (Detrol LA, Pfizer); generics remain available.	10/1/19
Morphine sulfate injection PCA glass vial (ICU Medical); morphine sulfate injection remains available from other manufacturers.	10/2/19
Olaratumab injection (Lartruvo, Eli Lilly and Co.); withdrawn after additional study results demonstrated no survival advantage. Patients may continue therapy through an access program through the manufacturer or be switched to alternative therapies.	10/2/19
Morphine sulfate and naltrexone HCl extended-release capsules (Embeda, Pfizer); alternative abuse-deterrent morphine dosage forms remain available.	10/7/19
Lamotrigine tablets (Teva); generics remain available from other manufacturers	10/15/19
Doxycycline hyclate capsules (Teva); generics remain available from other manufacturers.	10/15/19
Bosentan tablets (Janssen); generics remain available from other manufacturers.	10/15/19
Ifosfamide/mesna kit (Teva); ifosfamide and mesna remain available separately.	10/18/19
Hydrochlorothiazide capsules 12.5 mg (Microzide, Allergan); generics remains available.	10/22/19
Darifenacin hydrobromide extended release tablets (Par); remains available from other manufacturers.	10/30/19
Azacitidine injection (Teva); remains available from other manufacturers.	10/30/19
Divalproex sodium extended release tablets (Par); remains available from other manufacturers.	10/31/19

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Trifarotene/ Aklief/ Galderma Lab	Topical treatment of acne vulgaris in patients 9 years of age and older	10/4/19
Brolucizumab-dbll / Beovu / Novartis Pharmaceuticals Corp	Intravitreal injection: treatment for neovascular (wet) age-related macular degeneration (AMD)	10/7/19
Afamelanotide/ Scenesse /Clinuvel	Subcutaneous implant used to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP).	10/8/19
Fluorodopa F18 injection / Feinstein Institute for Medical Research	Radioactive diagnostic agent for use in positron emission tomography (FDOPA PET scan) to visualize dopaminergic nerve terminals in the striatum for the evaluation of adult patients with suspected Parkinsonian syndromes	10/10/19
Lasmiditan/ Reyvow / Eli Lilly and Company	Acute (active but short-term) treatment of migraine with or without aura in adults	10/11/19
Elexacaftor-Ivacaftor-Tezacaftor / Trikafta / Vertex Pharmaceuticals	Treatment of cystic fibrosis in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene.	10/21/19
Diroximel fumarate delayed-release capsules / Vumerity / Alkermes	Treatment of relapsing forms of multiple sclerosis; Metabolized to monomethyl fumarate, the same active metabolite as dimethyl fumarate – approval based on bioavailability studies	10/29/19

New Indications:	***Description***	***Date Approved***
Sacubitril and valsartan / Entresto / Novartis	Treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older	10/1/19
Emtricitabine and tenofovir alafenamide / Descovy / Gilead	Use in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex	10/3/19
Cobicistat / Tybost / Gilead	Use with darunavir in combination with other antiretroviral agents in the treatment of HIV-1 infection in pediatric patients weighing at least 40 kg	10/3/19
Rivaroxaban / Xarelto / Janssen	Prophylaxis of venous thromboembolism in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding	10/11/19
Baloxavir marboxil / Xofluza / Genentech	Treatment of influenza in patients 12 years and older who are at high risk for developing influenza-related complications and have been symptomatic for no more than 2 days	10/16/19
Romiplostim / Nplate / Amgen	Treatment of thrombocytopenia in adult patients with immune thrombocytopenia who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy	10/17/19
Dapagliflozin / Farxiga / AstraZeneca & Dapagliflozin and metformin / Xigduo XR / AstraZeneca	Reduce the risk of hospitalization for heart failure in patients with type 2 diabetes mellitus and established cardiovascular disease or multiple CV risk factors	10/18/19
Ravulizumab / Ultomiris / Alexion Pharmaceuticals Inc	Treatment of atypical hemolytic uremic syndrome in adults and pediatric patients one months and older	10/18/19
Etanercept-szzs / Erelzi / Sandoz	Treatment of psoriatic arthritis and adult plaque psoriasis	10/18/19
OnabotulinumtoxinA / Botox / Allergan	Treatment of lower limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy	10/18/19
Treprostinil / Orenitram / United Therapeutics	Treatment of pulmonary arterial hypertension to delay disease progression	10/18/19
Insulin aspart / Fiasp / Novo Nordisk	Administration by continuous subcutaneous infusion using an insulin pump in the management of diabetes	10/21/19
Ustekinumab / Stelara / Janssen	Treatment of adults with moderately to severe active ulcerative colitis	10/21/19
Levetiracetam / Keppra & Keppra XR / UCB	Use as monotherapy in treatment of partial-onset seizures in patients 1 month and older (Keppra) and 12 years and older (Keppra XR)	10/23/19
Niraparib / Zejula / Tesaro	Treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency positive status	10/23/19
Delafloxacin / Baxdela / Melintra Therapeutics	Treatment of adults with community-acquired bacterial pneumonia caused by designated susceptible bacteria	10/25/19

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Benralizumab / Fasenra / AstraZeneca	Autoinjector: 30 mg/mL; for patient or caregiver administration in the treatment of severe eosinophilic asthma	10/3/19
Dexamethasone / Hemady / Dexcel Pharmaceuticals	Tablet: 20 mg; for use in combination with other anti-myeloma products for the treatment of adults with multiple myeloma	10/3/19
Cetirizine HCl / Quzyttir / TerSera Therapeutics LLC	Injection: 10 mg/mL; IV use for the treatment of acute urticaria in adults and children 6 months and older (See attached drug summary)	10/4/19
Teriparatide / Bonsity / Pfenex	Injection pen: 620 mcg/2.48 mL, providing 28 daily 20 mcg doses of the teriparatide (Forteo) biosimilar	10/4/19
Asenapine / Secuado / Noven Pharmaceuticals	Transdermal: treatment for adults with schizophrenia (See attached drug summary)	10/11/19
Biorphen / phenylephrine HCl injection / Eton Pharmaceuticals	Ready to use formulation for treatment of clinically important hypotension resulting primarily from anesthesia-associated vasodilation	10/21/19
Minocycline / Amzeeq / Foamix Pharmaceuticals	Topical foam 4%; treatment of acne	10/21/19

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Trifarotene 0.005% cream/ Aklief / Galderma Laboratories	
Generic Name / Brand Name / Company	Trifarotene cream/ Aklief / Galderma Laboratories
Date of approval	10/4/19
Drug Class (Mechanism of Action if novel agent)	Retinoid; retinoic acid receptor (RAR) agonist with activity at the gamma subtype of RAR
Indication	Topical treatment of acne vulgaris in patients 9 years of age and older
Comparative agent – Therapeutic interchange?	Tretinoin, adapalene, tazarotene
Dosage forms/strengths	Cream: 0.005%
Common Dose/sig	Apply to a thin layer to the affected area once daily, in the evening, on clean and dry skin
DEA Schedule	None
Date of market availability	November 2019
Similar Medication Names	Adapalene, trifluridine
Clinical Use Evaluation	
Common Adverse Effects	≥ 1%: Application site irritation, application site pruritis, and sunburn
Severe Adverse Effects	Erythema, scaling, dryness, stinging/burning
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 less than 9 years of age.
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	No contraindications in labeling Warnings: Skin irritation: can cause erythema, scaling, dryness, and stinging/burning. Manage skin irritation with a moisturizer following initiation of treatment, and if appropriate, reduce the frequency of application, suspend, or discontinue use. Ultraviolet light and environmental exposure: minimize sunlight and sunlamp exposure. Use sunscreen and protective clothing over treated areas when exposure cannot be avoided.
Special administration technique or considerations	Topical use only. One pump actuation should cover the face (i.e., forehead, cheeks, nose, and chin). Two pump actuations should cover the lower trunk (i.e., reachable upper back, shoulders, and chest. One additional pump may be used for middle and lower back if acne is present. Moisturizer use is recommended as frequently as needed following initiation of treatment.
Prepared by	Brittany Craft
Source	Aklief (trifarotene) [prescribing information]. Fort Worth, TX: Galderma Laboratories, L.P. October 2019.

Brolucizumab-dbll / Beovu / Novartis	
Generic Name / Brand Name / Company	Brolucizumab-dbll / Beovu / Novartis
Date of approval	10/7/19
Drug Class (Mechanism of Action if novel agent)	Human vascular endothelial growth receptor (VEGF) inhibitor; binds to three major isoforms of VEGF-A (e.g. $VEGF_{110}$, $VEGF_{121}$, and $VEGF_{165}$) and prevents interaction with VEGFR-1 and VEGFR-2 leading to suppression of endothelial cell proliferation, neovascularization, and vascular permeability.
Indication	Neovascular (wet) age-related macular degeneration
Comparative agent – Therapeutic interchange?	Ranibizumab, aflibercept, bevacizumab (off-label use), pegaptanib
Dosage forms/strengths	Intravitreal injection: 6 mg/0.05 mL solution in a single-dose vial
Common Dose/sig	Administer 6 mg (0.05 mL of 120 mg/mL solution) monthly (approximately 25 to 31 days) for the first three doses, followed by 6 mg (0.05 mL) once every 8 to 12 weeks
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Bevacizumab
Clinical Use Evaluation	
Common Adverse Effects	≥ 5%: vision blurred (10%), cataract (7%), conjunctival hemorrhage (6%), eye pain (5%), and vitreous floaters (5%)
Severe Adverse Effects	Thromboembolic events, endophthalmitis, retinal detachments, and hypersensitivity reactions
Severe Drug-Drug Interactions	Drug interaction studies have not been conducted
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 adjustments is necessary. The effect of severe renal impairment or any degree of hepatic impairment on the pharmacokinetics of brolucizumab is unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: Ocular or periocular infections, active intraocular inflammation, and hypersensitivity to brolucizumab or its excipients Warnings: Endophthalmitis and retinal detachments may occur following injection. Patients should report any symptoms (e.g. eye pain, redness of the eye, photophobia, blurring of the vision). Acute increases in intraocular pressure (IOP) have been reported within 30 minutes of injection. IOP and perfusion of the optic nerve head must be monitored and managed appropriately. Thromboembolic events have been observed following intravitreal use of VEGF inhibitors.
Special administration technique or considerations	The injection should be given immediately after preparation of the dose and must be administered by a qualified physician. Intraocular pressure should be monitored immediately after administration.
Prepared by	Brittany Craft
Source	Beovu (brolucizumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals, October 2019.

Afamelanotide / Scenesse / Clinuvel	
Generic Name / Brand Name / Company	Afamelanotide / Scenesse / Clinuvel
Date of approval	10/8/19
Drug Class (Mechanism of Action if novel agent)	Melanocortin receptor agonist and binds predominantly to MC1-R; is a synthetic tridecapeptide and a structural analog of α-melanocyte stimulating hormone (α-MSH).
Indication	To increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP).
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Implant: 16 mg; controlled-release dosage form
Common Dose/sig	Administer subcutaneously every 2 months
DEA Schedule	None
Date of market availability	Within 12 months
Similar Medication Names	Afatinib, senna
Clinical Use Evaluation	
Common Adverse Effects	> 2%: implant site reaction, nausea, oropharyngeal pain, cough, fatigue, dizziness, skin hyperpigmentation, somnolence, melanocytic nevus, respiratory tract infection, non-acute porphyria, and skin irritation.
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Drug interaction studies have not been conducted.
Severe Drug-Food Interactions	None reported
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	The effect of renal or hepatic impairment on the pharmacokinetics of afamelanotide is unknown.
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Contraindications: None in labeling Warnings: Skin monitoring: can lead to generalized increased skin pigmentation and darkening of pre-existing nevi and ephelides due to its pharmacologic effect. Full body examination twice yearly is recommended to monitor pre-existing and new skin pigmentary lesions.
Special administration technique or considerations	Administered by a healthcare professional (proper training should be completed prior to administration). Allow the carton containing afamelanotide to gradually warm up to ambient temperature prior to implantation. Identify the insertion site 3 to 4 cm above the anterior supra-iliac crest and disinfect the skin surface. The area of insertion may be anesthetized if deemed necessary. Implant will be inserted into the subcutaneous layer after inserting the cannula at a 30 to 45-degree angle and loading the implant into the cannula while maintaining aseptic precautions. Verify that no implant or implant portion remains in the cannula prior to full removal of the stylet (obturator) and the cannula. The skin should be palpated to verify the correct insertion and placement of the implant. Apply dressing to the insertion site and leave in place for 24 hours. Monitor the patient for 30 minutes after administration.
Prepared by	Brittany Craft
Source	Scenesse (afamelanotide) [prescribing information]. West Menlo Park, CA: CLINUVEL Inc., October 2019.

Lasmiditan / Reyvow / Eli Lilly	
Generic Name / Brand Name / Company	Lasmiditan / Reyvow / Eli Lilly
Date of approval	10/11/19
Drug Class (Mechanism of Action if novel agent)	Serotonin 5-HT1F receptor agonist
Indication	Acute treatment of migraine with or without aura in adults
Comparative agent – Therapeutic interchange?	Triptans (eg, sumatriptan)
Dosage forms/strengths	Tablets: 50 mg, 100 mg
Common Dose/sig	50 mg, 100 mg, or 200 mg orally as needed with no more than 1 dose every 24 hours
DEA Schedule	To be determined after DEA Review
Date of market availability	Pending DEA scheduling; likely early 2020
Similar Medication Names	Lasix, Reyataz
Clinical Use Evaluation	
Common Adverse Effects	≥5%: dizziness, fatigue, paresthesia, sedation
Severe Adverse Effects	Hypersensitivity, serotonin syndrome, dizziness, sedation
Severe Drug-Drug Interactions	Caution with alcohol or other CNS depressant drugs. Risk of serotonin syndrome with other serotonergic medications. Heart rate reduction with concomitant heart rate lowering drugs. Avoid concomitant P-glycoprotein and Breast Cancer Resistant Protein (BCRP) substrates.
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.
Renal or Hepatic Dosing	Renal: no adjustment necessary Hepatic: no adjustment necessary for mild or moderate impairment (Child-Pugh A and B), not recommended in severe impairment (Child-Pugh C).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications in the product labeling. Warnings: Do not perform tasks requiring mental alertness within 8 hours of taking lasmiditan Serotonin syndrome Use caution in patients using other CNS depressants Using migraine-treating drugs for more than 10 days per month may cause medication overuse headaches
Special administration technique or considerations	May be taken with or without food. No more than one dose should be taken in 24 hours; a second dose has not been shown to be effective for the same migraine attack.
Prepared by	Jordan Erickson
Source	Reyvow (lasmiditan) [prescribing information]. Indianapolis, IN: Eli Lilly and Company, October 2019.

Elexacaftor-Ivacaftor-Tezacaftor / Trikafta / Vertex Pharmaceuticals	
Generic Name / Brand Name / Company	Elexacaftor-Ivacaftor-Tezacaftor / Trikafta / Vertex Pharmaceuticals
Date of approval	10/21/19
Drug Class (Mechanism of Action if novel agent)	Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator; elexacaftor and tezacaftor bind to different sites on the CFTR protein and facilitate the cellular processing of F508del-CFTR to increase amounts of CFTR protein delivered to the cell surface. Ivacaftor potentiates the gating of the CFTR protein at the cell surface. This results in increased CFTR mediated chloride transport.
Indication	Treatment of cystic fibrosis in patients 12 years and older who have at least one F508del mutation in the CFTR gene.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Tablets: fixed dose combination containing elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg. Co-packaged with ivacaftor 150 mg tablets
Common Dose/sig	Morning dose: 2 elexacaftor-tezacaftor-ivacaftor tablets Evening dose: 1 ivacaftor 150 mg tablet Doses should be taken approximately 12 hours apart with fat-containing food
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Tezacaftor and ivacaftor
Clinical Use Evaluation	
Common Adverse Effects	≥5%: Headache, upper respiratory tract infection, abdominal pain, diarrhea, rash, nasal congestion, alanine aminotransferase increased, blood creatine phosphokinase increased, aspartate aminotransferase increased, rhinorrhea, rhinitis, influenza, sinusitis, blood bilirubin increase
Severe Adverse Effects	Liver function tests elevations, cataracts, rash, influenza
Severe Drug-Drug Interactions	Avoid coadministration with strong CYP3A inducers; reduce dose with CYP3A inhibitors – avoid grapefruit
Severe Drug-Food Interactions	Grapefruit (CYP3A inhibitor); administer with fat-containing foods
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver function tests
Used in Pediatric Areas	For patients 12 and older
Renal or Hepatic Dosing	No adjustment for mild to moderate renal impairment; has not been studied in severe renal impairment or end-stage renal disease. Not recommended for patients with severe hepatic impairment (Child-Pugh Class C); not recommended in patients with moderate hepatic impairment (Child-Pugh Class B) unless benefit exceeds risk; in patients with moderate hepatic impairment, it should be used with caution and at a reduced dose (no evening ivacaftor dose).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications in product labeling. Potential for increased liver enzymes; assess every 3 months for the first year of treatment and annually thereafter. Baseline and follow-up ophthalmologic examinations recommended.
Special administration technique or considerations	Take with fat-containing food
Prepared by	Kevin Kelly
Source	Trikafta (elexacaftor, tezacaftor and ivacaftor) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated, October 2019.

Cetirizine HCl Injection / Quzyttir / TerSera Therapeutics LLC	
Generic Name / Brand Name / Company	Cetirizine HCl Injection / Quzyttir / TerSera Therapeutics LLC
Date of approval	10/4/19
Drug Class (Mechanism of Action if novel agent)	Low-sedating histamine H1 antagonist
Indication	Treatment of acute urticaria in adults and children 6 months and older
Comparative agent – Therapeutic interchange?	Diphenhydramine, hydroxyzine
Dosage forms/strengths	Injection: 10 mg/mL
Common Dose/sig	Adults/adolescents 12 years and older: 10 mg IV every 24 hours as needed Children 6 to 11 years: 5 mg or 10 mg IV every 24 hours as needed Children 6 months to 6 years: 2.5 mg IV every 24 hours as needed
DEA Schedule	None
Date of market availability	Pending
Similar Medication Names	Cetirizine HCl oral
Clinical Use Evaluation	
Common Adverse Effects	<1%: dysgeusia, headache, paresthesia, presyncope, dyspepsia, feeling hot, hyperhidrosis
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	Not applicable
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Assess renal and hepatic function in patients younger than 6 years
Used in Pediatric Areas	Indicated in patients 6 months and older.
Renal or Hepatic Dosing	No dosage adjustment required. Monitor for antihistamine side effects.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with known hypersensitivity to cetirizine HCl or any of the product ingredients, levocetirizine, or hydroxyzine. Not recommended in pediatric patients less than 6 years of age with impairment renal or hepatic function. Sedation has been reported in some patients; caution patients regarding operating machinery and cautiously administer with other CNS depressant medications.
Special administration technique or considerations	Administer IV push over 1 to 2 minutes. Can repeat every 24 hours as needed for acute urticaria.
Prepared by	Terri Levien
Source	Quzyttir (cetirizine) injection [prescribing information]. Lake Forest, IL: TerSera Therapeutics LLC; October 2019.

Asenapine Transdermal System / Secuado / Noven Pharmaceuticals	
Generic Name / Brand Name / Company	Asenapine Transdermal System / Secuado / Noven Pharmaceuticals
Date of approval	10/11/19
Drug Class (Mechanism of Action if novel agent)	Antipsychotic; effects on schizophrenia may be mediated through a combination of antagonist activity at the dopamine D2 and serotonin 5-HT2A receptors.
Indication	Schizophrenia in adults
Comparative agent – Therapeutic interchange?	Asenapine sublingual; injectable antipsychotics
Dosage forms/strengths	Transdermal system: 3.8 mg/24 hours, 5.7 mg/24 hours, 7.6 mg/24 hours
Common Dose/sig	Initial: 3.8 mg/24 hours patch topically once daily
DEA Schedule	None
Date of market availability	Not announced
Similar Medication Names	Asenapine sublingual, clonidine
Clinical Use Evaluation	
Common Adverse Effects	>5%: extrapyramidal disorder, application site reaction, weight gain
Severe Adverse Effects	Orthostatic hypotension, hyperglycemia, dyslipidemia, weight increased, leukopenia, neutropenia, hypersensitivity reactions, angioedema,
Severe Drug-Drug Interactions	Antihypertensive drugs: enhanced antihypertensive effect, monitor blood pressure. Strong CYP1A2 inhibitors: consider asenapine dose reduction Paroxetine (CYP2D6 substrate and inhibitor): reduce paroxetine dose by half.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Fasting plasma glucose and fasting lipid profile at baseline and periodically during treatment. CBC in patients with pre-existing low WBC.
Used in Pediatric Areas	Safety and efficacy have not been established.
Renal or Hepatic Dosing	No dosage adjustment in mild to severe renal impairment or mild to moderate hepatic impairment; contraindicated in severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: severe hepatic impairment, history of hypersensitivity to asenapine or any components of the patch. Warnings: When heat is applied to the transdermal system, both the rate and extent of absorption are increased. Application site reactions. Also consider class cautions: Avoid use in elderly with dementia-related psychosis, neuroleptic malignant syndrome, metabolic changes (hyperglycemia, dyslipidemia, weight gain), orthostatic hypotension, falls, leukopenia, neutropenia, agranulocytosis, QT prolongation, hyperprolactinemia, seizures, cognitive or motor impairment, body temperature regulation, dysphagia.
Special administration technique or considerations	Select a different application site each day for transdermal patch. Apply to the hip, abdomen, upper arm or upper back area.
Prepared by	Audrian Santos
Source	Asenapine (Secuado) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; October 2019.