Highlights of FDA Activities – 12/1/17 – 12/31/17

FDA Drug Safety Communications & Drug Information Updates:

Albumin Human 25% Solution (AlbuRx 25): Product Information Advisory – Fading Print on Label 12/1/17

During routine inspection of retained AlbuRx 25% samples, CSL Behring noted the potential for fading print on the labels particularly on the expiration dating on the patient tear off portion of the vial label. This is limited to 50 and 100 mL vial sizes. Vial labels should be inspected for readability and fading. If fading is evident, the lot number and expiration dating can be found on the carton. Additionally, the lot number is imprinted on the vial aluminum seal.

Limbrel Capsules, Primus Pharmaceuticals: FDA Advisory - Potentially Life-Threatening Health Problems 12/5/17

The FDA has recommended that Primus Pharmaceuticals, Scottsdale, Arizona, recall Limbrel, a capsule marketed to "manage the metabolic processes associated with osteoarthritis." Although the product is marketed as a medical food, the preliminary determination of the FDA investigation is that Limbrel is an unapproved new drug. The FDA reminds consumers not to use Limbrel due to the risk of drug-induced liver injury and hypersensitivity pneumonitis. Consumers are advised to stop taking this product immediately and contact their health care provider. Health care providers who are aware that their patients are taking Limbrel should advise them to stop using it

Pediatric Rare Disease Drug Development Draft Guidance: FDA Drug Information Update 12/6/17

The FDA issued a draft guidance outlining a new approach to develop new drug therapies for rare pediatric diseases. While Gaucher disease is the focus of the draft guidance, the purpose of the guidance is to facilitate drug development for rare pediatric diseases in general and promote the exploration of efficient drug development approaches for Gaucher and other similar rare diseases. The draft guidance is available on the FDA's website.

Warning to Companies Promoting Alternatives to Street Drugs: FDA Drug Information Update 12/12/17

The FDA issued warning letters to the marketers and distributers of Legal Lean Syrup, a drink, and Coco Loko, a "snortable" chocolate powder, for selling unapproved new drugs and misbranded drugs. Claims in the marketing materials for these agents promote them for use as alternatives to illicit street drugs, and the products as labeled may pose safety concerns.

New FDA Website to Provide Antimicrobial Breakpoint Information: Drug Information Update 12/12/17

The FDA launched a new website that will contain updated breakpoint information to help prescribers determine whether the organism causing a patient's infection is susceptible to particular antibacterial or antifungal drugs. The new site can be found at: Antimicrobial Susceptibility Test Interpretive Criteria

Draft Guidance For Drugs That Contain Nanomaterials 12/15/17

The FDA issued a draft guidance providing recommendations to industry engaged in developing human drug products in which a nanomaterial is present in the finished dosage form, including recommendations regarding investigational, premarket, and post-market submissions for these products. This draft guidance describes a risk-based approach to the regulation of these products, focusing on the characteristics of the nanomaterial, its intended use and application, and evaluating how its attributes may relate to product quality, safety, and efficacy.

Draft Guidance For Homeopathic Remedies 12/18/17

The FDA issued a draft guidance for regulating homeopathic remedies. The FDA announced it will concentrate on products that have: reported safety concerns, potentially dangerous ingredients, ingredients that are not listed on the label, or risks associated with the route of administration or intent to treat vulnerable individuals or serious or life-threatening conditions.

Gadolinium-based Contrast Agents (GBCAs) for MRI: Drug Safety Communication 12/19/17
The FDA is requiring a new class warning and other safety measures for all gadolinium-based contrast agents (GBCAs) for magnetic resonance imaging (MRI) concerning gadolinium remaining in patients' bodies, including the brain, for months to years after receiving these drugs. A new patient Medication Guide is required providing educational information that every patient will be asked to read before receiving a GBCA. The FDA is also requiring manufacturers of GBCAs to conduct human and animal studies to further assess the safety of these contrast agents. The FDA recommends that health care professionals should consider the retention characteristics of each agent when choosing a GBCA for patients who may be at higher risk for gadolinium retention. Linear GBCAs result in more retention and longer retention than macrocyclic GBCAs. Patients at higher risk include those requiring multiple lifetime doses, pregnant women, children, and patients with inflammatory conditions.

FDA Bans OTC Triclosan and 23 Other Ingredients for Lack of Sufficient Safety And Efficacy Data 12/19/17
The FDA has finalized a rule that bans the marketing of over-the-counter (OTC) healthcare antiseptic products containing triclosan or 23 other active ingredients without premarket review. The FDA will consider these products to be new drugs and will require manufacturers to gain approval through new drug applications. The FDA is giving manufacturers 1 year to reformulate or remove these products from the market, although manufacturers have already stopped using many of these ingredients.

Boxed Warning Removed For LABA/ICS Combo Drugs: Drug Safety Communication 12/20/17
Based on the FDA review of four large clinical safety trials showing that treating asthma with long-acting beta agonists (LABAs) in combination with inhaled corticosteroids (ICS) does not result in significantly more serious asthma-related side effects than treatment with ICS alone, the Boxed Warning about asthma-related death has been removed from the drug labels of medicines that contain both an ICS and LABA. A description of the four trials is now also included in the Warnings and Precautions section of the drug labels.

Updated Label of Nilotinib (Tasigna) Outlines Eligibility for Discontinuation of Treatment 12/22/17
The FDA allowed updated information to the product label of nilotinib for patients and health care providers regarding the conditions under which patients may be eligible to discontinue treatment. Patients with early (chronic) phase chronic myeloid leukemia who have been taking nilotinib for three years or more, and whose leukemia has responded to treatment according to specific criteria and testing, may be eligible to discontinue nilotinib. If treatment is stopped patients must be regularly monitored for disease recurrence.

Major Product Recalls Announced Through MedWatch:

Pharmacist Choice Alcohol Prep Pads by Simple Diagnostics: Recall – Lack of Sterility Assurance and Other Quality Issues 12/5/17
Simple Diagnostics recalled three lots of Pharmacist Choice Alcohol Prep Pads (UPC # 898302001050, NDC # 98302-0001-05), which were manufactured by Foshan Flying Medical Products Co. Ltd., located in China, due to the lack of sterility assurance and other quality issues. The affected lots (SD2070421201, SD2070420925, SD2070420601) were distributed between 10/18/2016 and 07/19/2017

Pantoprazole Sodium for Injection 40 Mg Per Vial: Recall - Presence of Glass Particles 12/20/17
AuroMedics Pharma LLC recalled one lot of Pantoprazole Sodium for Injection 40 mg per vial, to the hospital level (LOT # CPO170035, EXP. May 2019, NDC # 55150-202-10). The product was found to contain glass particles in the vial. The product was shipped out to customers on August 7, 2017 and was distributed to wholesalers and/or hospitals nationwide.

Linezolid Injection by Auromedics Pharma 600 mg/300 mL flexible bags: Recall - Presence of Mold 12/26/17
AuroMedics Pharma recalled one lot of Linezolid Injection 600 mg/300 mL flexible bags (NDC 55150 -242 -51, batch CLZ160007, expiration August 2018) to the hospital level. This batch was distributed from 5/15/17 through 8/14/17. The product was found to contain white particulate matter that has been identified as mold.

Dietary Supplement Recalls & Public Notifications

In December, the FDA issued notifications to the public regarding undeclared active ingredients in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Hidden/Undeclared Drug Ingredient(s)***
Blue Pearl*	Sexual enhancement	Sildenafil[1]
Bull Capsules*	Sexual enhancement	Sildenafil[1]
Chao Jimengnan*	Sexual enhancement	Sildenafil[1]

*Recalled

[1]Sildenafil may interact with nitrates to lower blood pressure to dangerous levels

New Product Shortages Reported by the FDA:	***Date Initially Posted***
Bumetanide Injection USP	12/13/17
Amoxapine Tablets (25 mg/50 mg/100 mg/150 mg)	12/19/17
Progesterone Injection, USP (500 mg per 10 mL)	12/21/17

Product Discontinuations/Withdrawals	***Date Posted***
Edrophonium Chloride (Enlon) Injection (Mylan): 150 mg per 15 mL in a multi-dose vial (NDC 67457-0190-15). All edrophonium products have been discontinued.	12/1/17
Edrophonium Chloride and Atropine Sulfate (Enlon-PLUS) Injection (Mylan): 10 mg per 1 mL edrophonium chloride and 0.14 mg per 1 mL in 5 mL single dose ampule, box of 10 ampules (NDC 67457-0192-05). All edrophonium products have been discontinued.	12/1/17
Norethindrone and Ethinyl Estradiol (Norinyl 1+35) tablet (Allergan): 6 blister packs per 1 carton, 1 kit in 1 blister pack (NDC 52544-0259-28). Generics remain available.	12/11/17
Lithium Carbonate capsules (Mylan): 150 mg capsule (NDC 00143-3188-01); 300 mg capsules (NDC 00143-3189-01, NDC 00143-3189-10); 600 mg capsule (NDC 00143-3190-01). Products available from other manufacturers.	12/12/17
Montelukast Sodium Chewable tablets (Mylan): 4 mg chewable tablets (NDC 00378-5204-93); 5 mg chewable tablets (NDC 00378-5205-93). Product available from other manufacturers.	12/12/17
Sertraline Hydrochloride tablets (Mylan): 25 mg tablets (NDC 00378-8011-05, NDC 00378-8011-01); 50 mg tablets (NDC 00378-8121-05, NDC 00378-8121-01); 100 mg tablets (NDC 00378-8127-05, NDC 00378-8127-01). Product available from other manufacturers.	12/12/17
Memantine Hydrochloride (NAMENDA) Oral Solution: 2 mg/ml, Packaging in 12 fl. oz. (360 mL) bottle (NDC 00456-3202-12). Generics remain available.	12/14/17
Fluvoxamine Tablets (Mylan Pharmaceuticals Inc.): Fluvoxamine Maleate Tablets 25 mg, 50 mg and 100 mg (NDCs: 0378-0407-01, 0378-0412-01 and 0378-0414-01). Product available from other manufacturers.	12/19/17
Acetazolamide (Diamox Sequels) Extended Release Capsules (Teva Pharmaceuticals): 500 mg/1 unit (NDC 51285-754-02). Generics remain available.	12/20/17
Albiglutide (Tanzeum) Injection (GlaxoSmithKline): 30-mg single-dose pen; carton of 4 (NDC 0173-0866-35); 50-mg single-dose pen; carton of 4 (NDC 0173-0867-35). Manufacturing and sale will be discontinued by July 2018; patients should be converted to alternative GLP-1 agonists.	12/21/17

New Drug Approvals:	***Description***	***Date Approved***
Trastuzumab-dkst / Ogivri / Mylan GmbH	First biosimilar to Herceptin (trastuzumab) for the treatment of patients with breast or metastatic stomach cancers whose tumors overexpress the HER2 gene	12/1/17
Semaglutide / Ozempic / Novo Nordisk	Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist for type 2 diabetes. *See attached drug summary.*	12/5/17
Insulin lispro / Admelog / Sanofi-Aventis	"Follow-on" alternative to Humalog for use in adults and pediatric patients 3 years and older with type 1 diabetes and adults with type 2 diabetes.	12/11/17
Ozenoxacin / Xepi / Medimetriks Pharmaceuticals	Bactericidal, non-fluorinated, quinolone cream for the topical treatment of impetigo. *See attached drug summary.*	12/11/17
Infliximab-qbtx / Ixifi / Pfizer	Biosimilar to Remicade; however, Pfizer does not plan to market Ixifi in the United States since they already market a Remicade biosimilar (infliximab-dyyb, Inflectra).	12/13/17
Netarsudil / Rhopressa / Aerie Pharmaceuticals	Rho Kinase Inhibitor. Indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. *See attached drug summary.*	12/18/17
Voretigene neparvovec-rzyl / Luxturna / Spark Therapeutics	Adeno-associated virus vector-based gene therapy. Luxturna works by sending a normal copy of the RPE65 gene directly to retinal cells, which can then produce the normal protein to restore vision. Indicated for biallelic RPE65 mutations. *See attached drug summary.*	12/19/17
Ertugliflozin / Steglatro / Merck Sharp & Dohme Corporation	Sodium glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus. *See attached drug summary.*	12/20/17
Macimorelin acetate / Macrilen / Aeterna Zentaris Inc.	It is an orally active growth hormone secretagogue (ghrelin agonist). Indicated as a growth hormone (GH) stimulation test (ST) for the diagnosis of adult growth hormone deficiency (AGHD). *See attached drug summary.*	12/20/17
Angiotensin II / Giapreza / La Jolla Pharmaceutical	Angiotensin ll is a vasoconstrictor used to increase blood pressure during septic or other distributive shock. *See attached drug summary.*	12/21/17

New Indications:	***Description***	***Date Approved***
Ixekizumab / Taltz / Lilly	Treatment of adults with active psoriatic arthritis	12/1/17
Evolocumab / Repatha / Amgen	To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease	12/1/17
Mepolizumab / Nucala / GlaxoSmithKline	Treatment of adults with eosinophilic granulomatosis with polyangiitis (EGPA, formerly known as Churg-Strauss Syndrome); a rare autoimmune disease that causes vasculitis.	12/12/17
Hydrogen Peroixde / Eskata / Aclaris Therapeutics, Inc	Hydrogen peroxide 40% topical solution pen for in-office application for the treatment of raised seborrheic keratoses.	12/14/17
Tofacitinib / Xeljanz & Xeljanz XR / Pfizer	Treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other DMARDs.	12/14/17
Cabozanitib / Cabometyx / Exelixis	First-line therapy for advanced renal cell carcinoma	12/19/17
Bosutinib / Bosulif / Pfizer	Treat adults with newly-diagnosed chronic phase Philadelphia chromosome positive chronic myelogenous leukemia	12/19/17

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Glycopyrrolate inhalation solution / Lonhala Magnair / Sunovion	Nebulized long-acting muscarinic antagonist for long-term maintenance treatment of COPD; uses the eFlow portable nebulizer to deliver a dose over 2-3 minutes. *See attached drug summary.*	12/5/17
Hydroxyurea /Siklos/ Meduik USA	Hydroxyurea formulation indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises; Available as 100 mg tablets and functionally triple-scored 1,000 mg tablets. *See attached drug summary.*	12/21/17
Brimonidine tartrate 0.025% ophthalmic solution / Lumify / Bausch & Lomb	OTC formulation of brimonidine for treatment of ocular redness	12/22/17
Valsartan oral solution / Prexxartan / Medicure	Valsartan 4 mg/mL oral grape-flavored solution indicated for the treatment of hypertension in adults and children 6 years and older, heart failure, and after a myocardial infarction.	12/19/17

Compiled by:	
Terri Levien, Pharm.D. Kalvin Stoker, Pharm.D., PGY1 Drug Information Resident Mira Kim, Pharm.D. Candidate 2018 Kyle Roxby, Pharm.D. Candidate 2018 Nichole Alexander, Pharm.D. Candidate 2019 Daniel Rutter, Pharm.D. Candidate 2018	**Drug Information Center** College of Pharmacy Washington State University PO Box 1495 Spokane, WA 99210-1495 (509) 358-7662 Pharmacy.druginfo@wsu.edu

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Semaglutide / Ozempic / Novo Nordisk	
Generic Name / Brand Name / Company	Semaglutide / Ozempic / Novo Nordisk
Date of approval	12/5/2017
Drug Class (Mechanism of Action if novel agent)	Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist
Indication	To improve glycemic control in Type 2 diabetes mellitus as an adjunct to diet and exercise
Comparative agent – Therapeutic interchange?	Exenatide (Byetta/Bydureon), liraglutide (Victoza, Saxenda), lixisenatide (Lyxumia), dulaglutide (Trulicity)
Dosage forms/strengths. Common Dose/sig	Each 1.5 mL pen contains 2 mg of semaglutide (1.34 mg/1 mL) and can deliver doses of 0.25 mg or 0.5 mg per injection, or 1 mg per injection Start therapy at 0.25 mg per week for the first four weeks then increase to 0.5 mg for four weeks. If more glycemic control is needed at this time increase the dose to 1 mg weekly.--
DEA Schedule	None
Date of market availability	1st quarter 2018
Similar Medication Names	Dulaglutide, liraglutide
Clinical Use Evaluation	
Common Adverse Effects	≥5%: nausea, vomiting, diarrhea, abdominal pain, constipation (delayed gastric emptying)
Severe Adverse Effects	Hypoglycemia when used with insulin or insulin secretagogues, gastrointestinal reactions, pancreatitis
Severe Drug-Drug Interactions	Additive hypoglycemic affect with insulin and insulin secretagogues
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Blood glucose and A1C; renal function in patients with severe adverse gastrointestinal reactions
Used in Pediatric Areas	Efficacy and safety not established
Renal or Hepatic Dosing	No renal or hepatic dose adjustments established
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with endocrine neoplasia syndrome type 2. Warnings: thyroid C-cell tumor risk, pancreatitis, diabetic retinopathy, sharing pen between patients, additive hypoglycemia with insulin or insulin secretagogues, acute kidney injury, hypersensitivity.
Special administration technique or considerations	Attach a new needle per each administration Turn the dose selector until a drop appears and a zero lines up in the window Turn the dose selector to the actual dose (0.25 mg, 0.5 mg, 1 mg) Subcutaneously inject the dose at a 90 degree angle and hold the pen dispenser down until the dose window reads zero. Inject subcutaneously in the thigh, abdomen or upper arm. Administered once a week at any time of day with or without food. If dose is missed administer within 5 days of missed dose Store unused pens in the refrigerator. Store the pen that is in use for 56 days either at room temperature or in the refrigerator.--
Prepared by	Nichole P Alexander Pharm D 2019 candidate
Source	Ozempic [Prescribing information] Plainsboro, NJ: Novo Nordisk Inc.; December 2017

Glycopyrrolate inhalation solution / Lonhala Magnair / Sunovion	
Generic Name / Brand Name / Company	Glycopyrrolate inhalation solution / Lonhala Magnair / Sunovion
Date of approval	New formulation approval - 12/5/17
Drug Class (Mechanism of Action if novel agent)	Long-acting muscarinic antagonist (LAMA)
Indication	Long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema
Comparative agent – Therapeutic interchange?	Ipratropium available for nebulization; no other LAMA is available for nebulization
Dosage forms/strengths. Common Dose/sig	Inhalation solution in a unit-dose single-use vial. Each 1 mL vial contains 25 mcg of glycopyrrolate. Recommended dosing: inhalation of the contents of one 25 mcg vial twice-daily using Magnair nebulizer system (1 vial in the morning and 1 vial in the evening).
DEA Schedule	Not scheduled
Date of market availability	Spring 2018
Similar Medication Names	Glycopyrrolate
Clinical Use Evaluation	
Common Adverse Effects	Common (> 2%): dyspnea and urinary tract infection
Severe Adverse Effects	Paradoxical bronchospasm
Severe Drug-Drug Interactions	May interact additively with concomitantly used anticholinergic medications.
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 not established; not indicated for use in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustments required for patients with hepatic impairment or mild to moderate renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with hypersensitivity to glycopyrrolate or any of the product ingredients. Warnings and Precautions: • Do not initiate in acutely deteriorating COPD or to treat acute symptoms • If paradoxical bronchospasm occurs, discontinue immediately and institute alternative therapy • Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a physician immediately if symptoms occur. • Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder neck obstruction and instruct patients to consult a physician immediately if symptoms occur
Special administration technique or considerations	Vial contents should only by administer with Magnair nebulizer. Administer at the same time each day More frequent administration or a greater number of inhalations (more than 1 vial twice daily) is not recommended. Vials should be stored in foil pouch and removed only immediately before use.
Prepared by	Mira Kim, PharmD Candidate 2018
Source	Lonhala Magnair [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals, Inc.; December 2017.

Ozenoxacin / Xepi / Medimetriks Pharmaceuticals	
Generic Name / Brand Name / Company	Ozenoxacin / Xepi / Medimetriks Pharmaceuticals
Date of approval	12/11/2017
Drug Class (Mechanism of Action if novel agent)	Bactericidal, non-fluorinated, quinolone cream. The mechanism of action involves the inhibition of bacterial DNA replication enzymes, DNA gyrase A and topoisomerase IV.
Indication	Topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes*
Comparative agent – Therapeutic interchange?	Topical mupirocin or retapamulin are alternatives
Dosage forms/strengths. Common Dose/sig	Cream: 1% in 10 g, 30 g, and 45 g tubes Apply a thin layer to the affected area twice daily for 5 days
DEA Schedule	None
Date of market availability	1st quarter 2018
Similar Medication Names	Xepin, Xepat
Clinical Use Evaluation	
Common Adverse Effects	None that were common
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	No severe interactions reported
Severe Drug-Food Interactions	None reported
Important Labs Values to assess prior to order entry or at point of clinical follow up.	No lab monitoring required. Monitor for impetigo symptom improvement and resolution.
Used in Pediatric Areas	Adult and pediatric patients 2 months of age and older
Renal or Hepatic Dosing	Very low levels of systemic absorption; no dose adjustments necessary.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Prolonged use may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur during therapy, discontinue use and institute appropriate supportive measures.
Special administration technique or considerations	Wash hands after applying cream. The treated area may be covered with a sterile bandage or gauze dressing. Reassess therapy if there is no improvement in symptoms within 3 days after starting use.
Prepared by	Nichole P Alexander Pharm D 2019 candidate
Source	Xepi [Prescribing information] Fairfield, NJ: Medimetriks Pharmaceuticals Inc.; December 2017

Netarsudil / Rhopressa / Aerie Pharmaceuticals	
Generic Name / Brand Name / Company	Netarsudil / Rhopressa / Aerie Pharmaceuticals
Date of approval	12/18/2017
Drug Class (Mechanism of Action if novel agent)	Rho kinase inhibitor - relaxes the trabecular meshwork through inhibition of the actin cytoskeleton contractile tone of smooth muscle. This increases aqueous outflow directly through the trabecular meshwork, and reduces intraocular pressures in a range similar to prostaglandins.
Indication	Indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
Comparative agent – Therapeutic interchange?	None in this class
Dosage forms/strengths. Common Dose/sig	Ophthalmic solution 0.02% (2.5 mL fill in a 4 mL container) One drop into the affected eye(s) once daily in the evening
DEA Schedule	None
Date of market availability	Anticipated availability by mid-second quarter of 2018
Similar Medication Names	None

Clinical Use Evaluation	
Common Adverse Effects	Conjunctival hyperemia (53%), corneal verticillata (20%), instillation site pain (20%), conjunctival hemorrhage (20%), instillation site erythema (5-10%), corneal staining (5-10%), blurred vision (5-10%), increased lacrimation (5-10%), erythema of eyelid (5-10%), reduced visual acuity (5-10%)
Severe Adverse Effects	None
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.	No lab monitoring required.
Used in Pediatric Areas	Safety and effectiveness in pediatric have not been established
Renal or Hepatic Dosing	No dosage adjustment required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products.
Special administration technique or considerations	Contains benzalkonium chloride, which may be absorbed by soft contact lenses; remove contact lenses prior to instilling ophthalmic solution into eye(s); may reinsert contact lenses 15 minutes following its administration One missed dose: Continue with the next dose in the evening; twice a day dosing is not well tolerated and is not recommended Concomitant use with other topical ophthalmic drug products to lower IOP: Administer each drug product >5 minutes apart Storage: Unopened bottle: Store at 2-8°C (36-46°F) until opened. Open bottle: Store at 2-25°C (36-77°F) for up to 6 weeks
Prepared by	Nichole P Alexander Pharm D 2019 candidate
Source	Rhopressa [Prescribing information] Irvine, CA: Aerie Pharmaceuticals Inc.; December 2017

Voretigene neparvovec-rzyl / Luxturna / Spark Therapeutics	
Generic Name / Brand Name / Company	Voretigene neparvovec-rzyl / Luxturna / Spark Therapeutics
Date of approval	12/19/2017
Drug Class (Mechanism of Action if novel agent)	Adeno-associated virus vector-based gene therapy - The RPE65 gene normally provides instructions for making an enzyme that is essential for normal vision. When there are mutations, that process is blocked, resulting in impaired vision. This gene therapy works by sending a normal copy of the RPE65 gene directly to retinal cells, which can then produce the normal protein to restore vision.
Indication	Indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy (Leber congenital amaurosis). Patients must have viable retinal cells as determined by the treating physician
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Suspension for sub-retinal injection, supplied in a 0.5 mL extractable volume in a single-dose 2 mL vial for a single administration in one eye. The supplied concentration ($5x10^{12}$ vector genomes (vg)/mL) requires a 1:10 dilution prior to administration. The diluent is supplied in two single-use 2-mL vials. The recommended dose for each eye is 1.5×10^{11} vg, administered by sub-retinal injection in a total volume of 0.3 mL
DEA Schedule	None

Date of market availability	Late 1st quarter 2018
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	>5%: conjunctival hyperemia, cataract, increased intraocular pressure, retinal tear, dellen (thinning of the corneal stroma), macular hole, sub-retinal deposits, eye inflammation, irritation, pain, and maculopathy (wrinkling on the surface of the macula).
Severe Adverse Effects	Endophthalmitis
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.	No lab monitoring
Used in Pediatric Areas	Not recommended for patients younger than 12 months of age
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Endophthalmitis: Use proper aseptic injection technique and monitor for signs and symptoms of infection. Permanent decline in visual acuity: Monitor for visual disturbances. Retinal abnormalities: Monitor for macular abnormalities, retinal tears or breaks. Do not inject in the immediate vicinity of the fovea. Increased intraocular pressure: Monitor and manage intraocular pressure elevations. Expansion of intraocular air bubbles: Air travel and/or scuba diving is not recommended until any intraocular air bubbles have been absorbed. Cataract: Subretinal injection may result in cataract formation or increase in the rate of cataract progression
Special administration technique or considerations	Perform subretinal administration to each eye on separate days within a close interval, but no fewer than 6 days apart. Administer oral corticosteroids equivalent to prednisone at 1 mg/kg/day (maximum of 40 mg/day) for a total of 7 days (starting 3 days before administration of voretigene neparvovec to each eye), and followed by a tapering dose during the next 10 days.
Prepared by	Nichole P Alexander Pharm D 2019 candidate
Source	Luxturna [Prescribing information] Philadelphia, PA: Spark Therapeutics Inc.; December 2017

Ertugliflozin / Steglatro / Merck Sharp & Dohme Corp.	
Generic Name / Brand Name / Company	Ertugliflozin / Steglatro / Merck Sharp & Dohme Corp.
Date of approval	12/20/2017
Drug Class (Mechanism of Action if novel agent)	Sodium glucose co-transporter 2 (SGLT2) inhibitor - prevents the kidneys from reabsorbing glucose back into the blood
Indication	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus.
Comparative agent – Therapeutic interchange?	Other SGLT2 inhibitors • empagliflozin/Jardiance- Oral tablets 10-25 mg per day • canagliflozin/Invokana- Oral tablets 100-300 mg per day • dapagliflozin/Farxiga- Oral tablets 5-10 mg per day
Dosage forms/strengths. Common Dose/sig	Oral tablets: 5 mg and 15 mg Recommended starting dose is 5 mg once daily, taken in the morning, with or without food. Increase dose to 15 mg once daily in those tolerating treatment and needing additional glycemic control.

DEA Schedule	None
Date of market availability	Available
Similar Medication Names	empagliflozin
Clinical Use Evaluation	
Common Adverse Effects	Female genital mycotic infections (>5%)
Severe Adverse Effects	Allergic reactions, hypotension, hypoglycemia, ketoacidosis, acute kidney injury and impairment in renal function, urosepsis and pyelonephritis.
Severe Drug-Drug Interactions	Increased risk of hypoglycemia when used with insulin or secretagogues.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Blood glucose levels and A1C; assess renal function before initiating and periodically thereafter.
Used in Pediatric Areas	Safety and efficacy have not been established.
Renal or Hepatic Dosing	No dose adjustment is needed in patients with mild renal impairment or hepatic impairment. Do not use in patients with an estimated glomerular filtration rate (eGFR) below 30 mL/minute/1.73m^2 Initiation is not recommended in patients with an eGFR of 30 to less than 60 mL/minute/1.73m^2 Continued use is not recommended in patients with an eGFR persistently between 30 and less than 60 mL/min/1.73m^2
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated: Severe renal impairment, end stage renal disease, dialysis, and history of serious hypersensitivity reaction to the medication. Warnings: Monitor for hypotension especially in renal impairment, elderly and patients on diuretics; ketoacidosis; acute kidney injury and impairment in renal function; urosepsis and pyelonephritis; genital mycotic infections; increased LDL-C; lower limb amputation; and hypoglycemia when taken with insulin or secretagogues. This medication can cause a positive urine glucose test so monitoring should not be done with urine glucose readings. Monitoring should not be done with 1,5-AG assays due to unreliable results while on this medication.
Special administration technique or considerations	Administered in the morning, with or without food.
Prepared by	Nichole P Alexander Pharm D 2019 candidate
Source	Steglatro [Prescribing information] Whitehouse Station, NJ: Merck & Co., Inc.; December 2017

Macimorelin acetate / Macrilen / Aeterna Zentaris	
Generic Name / Brand Name / Company	Macimorelin acetate / Macrilen / Aeterna Zentaris
Date of approval	12/20/2017
Drug Class (Mechanism of Action if novel agent)	Diagnostic; macimorelin stimulates growth hormone (GH) release by activating GH secretagogue receptors present in the pituitary and hypothalamus
Indication	Indicated as a GH stimulation test for the diagnosis of adult growth hormone deficiency.
Comparative agent – Therapeutic interchange?	Arginine plus levodopa test, glucagon stimulation test, insulin tolerance test
Dosage forms/strengths. Common Dose/sig	Granules: 60 mg, for reconstitution in 120 mL of water (0.5 mg/mL) The recommended dose is a single oral dose of 0.5 mg/kg in patients fasted for at least 8 hours.

DEA Schedule	None
Date of market availability	1st quarter 2018
Similar Medication Names	Macrocin, Macrolid
Clinical Use Evaluation	
Common Adverse Effects	Dysgeusia (4.5%), dizziness (3.9%), headache (3.9%), fatigue (3.9%), nausea (3.2%), hunger (3.2%)
Severe Adverse Effects	QT_c prolongation
Severe Drug-Drug Interactions	QT_c prolongation drugs, potential for false positive test results with the use of strong CYP3A4 inducers, drugs affecting growth hormone release (somatostatin, insulin, glucocorticoids, cyclooxygenase inhibitors such as aspirin or indomethacin, clonidine, levodopa, and insulin, muscarinic antagonists such as atropine, anti-thyroid medication such as propylthiouracil, and growth hormone products).
Severe Drug-Food Interactions	Administered only after 8 hour fast.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Draw venous blood samples for GH determination at 30 minutes, 45 minutes, 60 minutes and 90 minutes after administration of the macimorelin solution. A GH serum level less than 2.8 ng/mL confirms the presence of adult growth hormone deficiency.
Used in Pediatric Areas	The safety and efficacy in pediatric patients has not been established
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Warnings: QT_c prolongation, potential for false positive test results with the use of strong CYP3A4 inducers, and potential for false negative test results in recent onset hypothalamic disease.
Special administration technique or considerations	Ensure patient has fasted for at least 8 hours before administration. Use a glass or transparent plastic container with graduation in milliliters to dissolve the entire contents of the pouch(es) in the appropriate volume of water. Mix the solution for 2-3 minutes. Draw up the exact volume required and transfer into a drinking glass. Use the solution within 30 minutes of being mixed and discard any left over after this time. Have the patient drink the solution in 30 seconds. Observe the patient for the duration of the test, drawing venous blood samples at 30, 45, 60, and 90 minutes after administration.
Prepared by	Nichole P Alexander Pharm D 2019 candidate
Source	Macrilen [Prescribing information] Charleston, SC: Aeterna Zentaris Inc.; December 2017

Hydroxyurea / Siklos / Medunik USA	
Generic Name / Brand Name / Company	Hydroxyurea / Siklos / Medunik USA
Date of approval	New Formulation approval- 12/21/17
Drug Class (Mechanism of Action if novel agent)	Antimetabolite (antineoplastic agent)
Indication	Indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises.
Comparative agent – Therapeutic interchange?	Hydroxyurea capsules 200-500 mg
Dosage forms/strengths. Common Dose/sig	Tablets: 100 mg and functionally triple-scored 1,000 mg tablet Initial dose: 20 mg/kg once daily. Calculate rounded doses to the nearest 50 mg or 100 mg strength. The dose may be increased by 5 mg/kg/day every 8 weeks, or sooner if a severe painful crisis occurs until a maximum tolerated dose or 35 mg/kg/day is reached if blood counts are in an acceptable range
DEA Schedule	None
Date of market availability	Not known
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	>5%: Infection, neutropenia, thrombocytopenia, gastrointestinal disorders, vitamin D deficiency, headache, fever
Severe Adverse Effects	Infections, neutropenia, thrombocytopenia, anemia, nausea, headache, fever
Severe Drug-Drug Interactions	Antiretroviral drugs, live vaccines
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor blood counts before initiation and every two weeks. Fetal hemoglobin (HbF) may be used to evaluate efficacy; levels can be obtained every 3 to 4 months.
Used in Pediatric Areas	Used in pediatric patients 2 years and older
Renal or Hepatic Dosing	Renal impairment: Reduce the dose by 50% (10 mg/kg/day) in patients with creatinine clearance less than 60 mL/min; monitor hematologic parameters closely. Hepatic impairment: close hematologic monitoring recommended.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: previous hypersensitivity to hydroxyurea or any of the product ingredients Warnings: Myelosuppression, embryo-fetal toxicity, cutaneous vasculitic toxicities, malignancies, and macrocytosis. Increased risk of adverse events with administration with antiretroviral drugs and live vaccines. May interfere with uric acid, urea, or lactic acid assays, rendering falsely elevated results in patients treated with hydroxyurea. Contraception use is recommended for females and males of reproductive potential while taking this medication and for six months after.
Special administration technique or considerations	Wear disposable gloves when handling tablets or bottles containing the drug. The 1,000 mg tablets have 3 score lines and can be split into 4 parts (250 mg each). Do not split the 100 mg tablets into smaller parts. For patients who are not able to swallow the tablets, these can be dispersed immediately before use in a small quantity of water in a teaspoon.
Prepared by	Nichole P Alexander Pharm D 2019 candidate
Source	Siklos [Prescribing information] Rosemont, PA: Medunik USA, Inc.; December 2017

Angiotensin II / Giapreza / La Jolla Pharmaceutical Company	
Generic Name / Brand Name / Company	Angiotensin II / Giapreza / La Jolla Pharmaceutical Company
Date of approval	12/21/2017
Drug Class (Mechanism of Action if novel agent)	Vasoconstrictor to increase blood pressure - angiotensin II acts in the central nervous system to increase antidiuretic hormone and on venous and arterial vessels' smooth muscle causing vasoconstriction. Additionally it works to increase aldosterone secretion, acting as an autocrine (paracrine), endocrine, and intracrine hormone.
Indication	To increase blood pressure in patients with septic or other distributive shock.
Comparative agent – Therapeutic interchange?	Phenylephrine, vasopressin, dobutamine, dopamine, norepinephrine, epinephrine
Dosage forms/strengths. Common Dose/sig	Injection: 2.5 mg/mL and 5 mg/2 mL (2.5 mg/mL) in a vial Starting dosage: 20 ng/kg/min via continuous intravenous infusion. Monitor blood pressure response and titrate every 5 minutes by increments of up to 15 ng/kg/min as needed to achieve or maintain target blood pressure. Do not exceed 80 ng/kg/min during the first 3 hours of treatment. Maintenance doses should not exceed 40 ng/kg/min. Doses as low as 1.25 ng/kg/min may be used.
DEA Schedule	None
Date of market availability	March 2018
Similar Medication Names	Angiotensin II Receptor Blockers
Clinical Use Evaluation	
Common Adverse Effects	Thromboembolic events (12.9%), thrombocytopenia (9.8%), tachycardia (8.6%), fungal Infection (6.1%), delirium (5.5%), acidosis (5.5%), hyperglycemia (4.3%), peripheral ischemia (4.3%), deep vein thrombosis (4.3%)
Severe Adverse Effects	Thromboembolic events
Severe Drug-Drug Interactions	Angiotensin converting enzyme (ACE) inhibitors (increase response to angiotensin II) and Angiotensin II Receptor Blockers (ARBs) (decrease response to angiotensin II)
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	No lab monitoring
Used in Pediatric Areas	The safety and efficacy in pediatric patients have not been established
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Use concurrent venous thromboembolism (VTE) prophylaxis due to risk of venous and arterial thrombotic and thromboembolic events. Caution overdose: can cause hypertension but effects are expected to be brief because the half-life of angiotensin II is less than one minute
Special administration technique or considerations	Administer as an intravenous infusion. A central venous line is recommended. Dilute in 0.9% sodium chloride to achieve a final concentration of 5,000 ng/mL or 10,000 ng/mL
Prepared by	Nichole P Alexander Pharm D 2019 candidate
Source	Giapreza [Prescribing information] San Diego, CA: La Jolla Pharmaceutical Company; December 2017