Highlights of FDA Activities – 10/1/15 – 10/31/15

FDA Drug Safety Communications & Drug Information Updates:

Hepatitis C Treatments Viekira Pak and Technivie: Risk of Serious Liver Injury 10/22/2015
Serious liver injury (eg, decompensation and liver failure) may result mainly in patients with underlying advanced liver disease treated with these hepatitis C treatments. Some of these adverse events resulted in liver transplantation or death. The FDA is requiring information about serious liver injury be added to the Contraindications, Warning and Precautions, Postmarketing Experience, and Hepatic Impairment sections of the drug labels for these products.

FDA requires drug interaction studies with potassium-lowering drug Kayexalate (sodium polystyrene sulfonate) 10/22/2015
The FDA is requiring the manufacturer of Kayexalate, Concordia Pharmaceuticals, to conduct studies to explore the potential of Kayexalate to bind other oral medications, which may affect the effectiveness of other drugs. The currently approved labeling describes the potential for Kayexalate to decrease lithium and thyroxine absorption, but extensive studies on other drug-drug interactions have not been performed. A similar drug that lowers potassium (patiromer, Veltassa) should be taken at least 6 hours before other medications The same recommendation should be applied to Kayexalate until these studies are completed.

No increased cardiovascular risks with Parkinson's disease drug entacapone 10/26/2015
A FDA safety review has found no clear evidence of increased risk of cardiovascular events (including heart attack and stroke) with use of entacapone for Parkinson's disease. Accordingly, there will be no changes made to the current recommendations for use of Comtan (entacapone) and Stalevo (a combination product of entacapone, carbidopa, and levodopa). A FDA alert in 2010 addressed a possible increased risk for cardiovascular events and death with Stalevo raised by the results of a single study and a meta-analysis that included that study. Carbidopa and levodopa have been widely used without showing increased cardiovascular risk; so the risk was thought to be related to entacapone. Novartis, which manufactures Stalevo, was required to study this potential risk and found no increased risk of cardiovascular adverse events with entacapone. In addition to the required study by the manufacturer, a second study found no association between the use of entacapone and an increased cardiovascular risk. The results of the original study, which was not designed to assess cardiovascular risks, were believed to be due to chance.

Major Product Recalls Announced Through MedWatch:

FDA Statement – Lack of Sterility Assurance: Chen Shwezin Inc., dba Park Compounding Pharmacy 10/03/15
During the FDA's recent inspection of Park Compounding Pharmacy's facility, investigators observed unsanitary conditions, including poor sterile production practices. The FDA is alerting health care professionals and patients not to use drug products intended to be sterile from Chen Shwezin Inc., doing business as Park Compounding Pharmacy, in Westlake Village, CA. Park Compounding Pharmacy has agreed to cease sterile operations, but the company has refused to recall its products.

Medline Industries, Inc.: Recall of Acetaminophen 500 mg, Lot # 45810, exp. May 2018 10/09/15
The 500 mg acetaminophen tablet, Tab 100/BT (OTC20101) NDC#53329-641-30, has been found to be mislabeled as "acetaminophen 325 mg" (OTC10101). This error is not easily identifiable by the user or prescriber, and could result in liver toxicity or liver failure if the product is taken at the maximum labeled dose. The lot was distributed nationwide from 6/12/15 through 9/18/15.

Qualgen LLC: Recall and Alert to Avoid use of Qualgen Products Marketed as Sterile 10/13/15
Lots 1 through 67 of products from Qualgen LLC compounded prior to 9/1/15, distributed nationwide, and intended to be sterile have been recalled due to a lack of sterility and quality assurance. The FDA recommended all sterile compounding operations cease until appropriate corrective actions were implemented by the facility; however, the company refused to cease sterile compounding operations prompting an FDA alert to avoid use of all Qualgen products marketed as sterile.

Downing Labs, LLC Sterile Compounded Products: Recall - Lack of Sterility Assurance 10/21/15
Downing Labs, LLC is recalling all lots of sterile products compounded and packaged by Downing Labs due to concerns over sterility assurance. The products were distributed nationwide and in the UK to patients and providers between 4/20/15 and 9/15/15.

Sanofi US: Recall of Auvi-Q (epinephrine injection, USP) Due to Potential Inaccurate Dosage Delivery 10/28/15
Sanofi US is voluntarily recalling all units of Auvi-Q epinephrine injection devices from lot number 2299596 through 3037230 which expire March 2016 through December 2016 due to potentially inaccurate dosage delivery. As of 10/26/15, there are 26 reports of suspected device malfunctions between the US and Canada. None of these cases are confirmed and there are no fatal outcomes among the suspected cases. Customers should immediately contact their healthcare provider for a prescription for an alternate epinephrine auto-injector. In the event of a life-threatening allergic reaction, patients should only use their Auvi-Q device if another epinephrine auto-injector is not available, and then call 911 or local emergency medical services. Sanofi US will reimburse patients for out of pocket costs incurred for the purchase of new epinephrine auto-injectors with proof of purchase.

Dietary Supplement Recalls & Public Notifications

In October, 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)***
Rhino 7 3000 and Rhino 7 Platinum 3000 capsules*	Male enhancement	Desmethyl carbondenafil, dapoxetine
Ultimate Herbal Slimcap	Weight loss	Sibutramine
NATUREAL	Weight loss	Sibutramine
Wild Sexx Capsules	Sexual enhancement	Sildenafil, tadalafil
Ultra SX Capsules	Sexual enhancement	Sildenafil
Super Dragon 6000 Capsules	Sexual enhancement	Sildenafil
Sex-Love Secret Code	Sexual enhancement	Sildenafil
Paradise Suplemento Natural Ultra Plus Capsules	Sexual enhancement	Sildenafil
APEXXX	Sexual enhancement	Sildenafil
Fuel Up High Octane	Sexual enhancement	Hydroxythiohomosildenafil
Fuel Up Plus	Sexual enhancement	Hydroxythiohomosildenafil
S.W.A.G.G.E.R. Extreme Capsules	Sexual enhancement	Sildenafil
Xtreme Fat Burner	Weight loss	Phenolphthalein, sildenafil
Tip-Top Shape	Weight loss	Sibutramine
Lishou Slimming Coffee	Weight loss	Sibutramine
Basha Nut 100% Fruit Soft Gel	Weight loss	Sibutramine

*Recalled

New Product Shortages Reported by the FDA:	***Date Initially Posted***
Mupirocin Calcium Nasal Ointment (2%)	10/14/15

Product Discontinuations/Withdrawals	***Date Posted***
Ioxilan Injection (Oxilan/Guerbett LLC) – Medical imaging product, discontinuation anticipated for April 2016.	10/06/2015
Metoprolol Tartrate Injection, USP (Lopressor; 5 mg/5mL; Novartis) – Discontinued for business reasons; generics remain available.	10/08/2015
Formoterol fumarate (FORADIL® AEROLIZER®, Merck Sharp & Dohme Corp.) Inhalation Powder – voluntary discontinuation by Novartis/Merck for business reasons. Inventory expected to be exhausted ~January 2016.	10/21/2015
Oxybutynin (GELNIQUE 3%, Actavis, Inc.) Gel 100 mL metered pump dispenser – discontinued for business reasons. Date of disruption in supply: March 2016. Oxybutynin 10% gel and other transdermal formulations remain available.	10/27/2015
Meloxicam (Mobic, Boehringer Ingelheim Pharmaceuticals, Inc.) Oral Suspension 7.5 mg/5 mL – permanent discontinuation for business reasons; generics remain available.	10/27/2015
Dipyridamole (Persantine®, Boehringer Ingelheim Pharmaceuticals, Inc.) Tablets 25, 50 mg (Persantine®); 25, 50, 75 mg (Boehringer Ingelheim generic) – permanent discontinuation of drug product as a result of a business decision, adequate market supply of Persantine® should last through May 2016 and dipyridamole generic through August 2017; other generics remain available.	10/27/2015
Morphine injection (15 mg/mL 20 ml vials and 10 mg/mL 10 mL vials from West-Ward. The manufacturer has discontinued manufacturing the multi-dose vials.	10/29/15

New Drug Approvals:	***Description***	***Date Approved***
Idarucizumab / Praxbind / Boehringer Ingelheim	Indicated in patients treated with dabigatran when reversal of anticoagulant effects are necessary; see attached drug summary	10/16/15
Coagulation Factor X (human) / Coagadex / Bio Products Laboratory	Indicted for replacement therapy for patients with hereditary Factor X deficiency	10/20/15
Patiromer / Veltassa / Relypsa	Indicated for treatment of adults with hyperkalemia; see attached drug summary.	10/21/15
Asfotase alfa / Strensiq / Alexion Pharmaceuticals	Indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP); see attached drug summary.	10/23/15
Trabectedin / Yondelis / Janssen	Indicated for patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen; see attached drug summary.	10/23/15
Talimogene laherparepvec / Imlygic / Amgen	Indicated for the treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery; see attached drug summary.	10/27/15
Glycopyrrolate inhalation powder / Seebri Neohaler / Novartis	Indicated for long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease	10/29/15

New Indications:	***Description***	***Date Approved***
Pembrolizumab / Keytruda / Merck&Co.	Indication expanded to treat patients with advanced (metastatic) non-small cell lung cancer whose disease has progressed after other treatments and with tumors that express PD-L1.	10/2/15
Simeprevir / Olysio / Janssen	Indication expanded to include treatment of chronic hepatitis C genotype 4.	10/5/15
Nivolumab / Opdivo / Bristol-Myers Squibb	Indication expanded to treat patients with non-squamous non-small cell lung cancer.	10/9/15

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Morphine sulfate / Morphabond / Inspirion Delivery Technologies LLC	Extended release abuse-deterrent formulation of morphine	10/2/15
Aripiprazole lauroxil extended-release injectable suspension / Aristada / Alkermes, Inc.	Extended release injection administered every four to six weeks to treat adults with schizophrenia.	10/5/15
Calcipotriene 0.005% & betamethasone dipropionate 0.064% foam / Enstilar / Leo Pharma	Topical treatment of plaque psoriasis in adults	10/16/15
Amphetamine extended-release oral suspension / Dyanavel XR / Tris Pharma	Extended-release suspension for once-daily administration for attention deficit/hyperactivity disorder in children 6 years and older	10/19/15
Meloxicam capsules / Vivlodex / Iroko Pharms	New low dose (5 mg and 10 mg strengths) of rapid dissolving meloxicam for the management of osteoarthritis pain	10/22/15
Irinotecan liposome / Onivyde / Merrimack Pharms	Liposomal formulation indicated for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy	10/22/15
Buprenorphine buccal film / Belbuca / Endo Pharms	Buccal film in 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg strengths for the management of severe pain requiring around-the clock, long-term opioid treatment and for which alternative treatment options are inadequate.	10/23/15
Indacaterol-glycopyrrolate inhalation powder / Utibron / Novartis Pharmaceuticals	Indicated for the treatment of chronic obstructive pulmonary disease.	10/29/15

Compiled by:

Terri Levien, Pharm.D.
Ross Bindler, Pharm.D., PGY2 Drug Information Resident
Anne Kim, Pharm.D., PGY2 Drug Information Resident
Renee Saxon, Pharm.D. Candidate 2016
Meleina Fraga, Pharm.D. Candidate 2016
Matthew Iguchi, Pharm.D. Candidate 2016
Stephanie Lind, Pharm.D. Candidate 2016

Drug Information Center
College of Pharmacy
Washington State University
PO Box 1495
Spokane, WA 99210-1495
(509) 358-7662
Pharmacy.druginfo@wsu.edu

Idarucizumab / Praxbind / Boehringer Ingelheim	
Generic Name / Brand Name / Company	Idarucizumab / Praxbind / Boehringer Ingelheim
Date of approval	10/16/15
Drug Class (Mechanism of Action if novel agent)	Dabigatran reversal agent. Humanized monoclonal antibody fragment that binds to dabigatran and its acylglucuronide metabolites with higher affinity than the binding affinity of dabigatran to thrombin, neutralizing the anticoagulant effect
Indication	For patients treated with dabigatran that need reversal of anticoagulant effects due to emergency surgery/urgent procedures or life-threatening or uncontrolled bleeding
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Dosage form/strength: 2.5 g/50 mL per vial Dose: 5 grams administered intravenously
DEA Schedule	None
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	IDArubicin – consider using idaruCIZUMAB lettering to differentiate
CLINICAL USE EVALUATION	
Common Adverse Effects	Headache, hypokalemia, confusion, fever, pneumonia, pyrexia
Severe Adverse Effects	Hypersensitivity, thromboembolic risk, serious adverse effects in patients with hereditary fructose intolerance
Severe Drug-Drug Interactions	None known. Idarucizumab is not affected by coagulation factor concentrates. Neutralization of dabigatran anticoagulant activity is not influenced by 50% hemodilution with routinely used volume replacement strategies.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	None
Used in Pediatric Areas	Safety and effectiveness has not been established
Renal or Hepatic Dosing	• No dose adjustment for renal impairment • No formal studies with hepatic impairment have been conducted
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Thrombotic risk: Patients may have disease states that predispose them to thromboembolic events; reversing dabigatran therapy puts patients at risk • Hypersensitivity reactions • Risks of serious adverse reactions in patients with hereditary fructose intolerance due to sorbitol excipient: hypoglycemia, hypophosphatemia, metabolic acidosis, increase in uric acid, acute liver failure with breakdown of excretory and synthetic function. Praxbind contains 4 g sorbitol.
Special administration technique or considerations	• Prior to use, unopened vial may be kept at room temperature (25°C) for up to 48 hours if stored in the original package in order to protect from light, or up to 6 hours when exposed to light • Store vials in the refrigerator at 2 to 8°C; do not freeze • Do not shake • Once solution is removed from the vial, administration should begin within 1 hour • Administer intravenously 5 g (2 vials) as two consecutive infusions or a bolus injection by injecting both vials consecutively one after another via syringe • A pre-existing IV line may be used.

	• Flush line with sterile 0.9% sodium chloride injection, USP solution prior to infusion • No other infusion should be administered in parallel via the same IV access • Dabigatran may be initiated 24 hours after administration of idarucizumab
Prepared by	Renee Saxon, Pharm. D. Candidate 2016

Patiromer for Oral Suspension / Veltassa / Relypsa Inc.	
Generic Name / Brand Name / Company	Patiromer / Veltassa / Relypsa Inc.
Date of approval	10/21/15
Drug Class (Mechanism of Action if novel agent)	Potassium removing agents; patiromer increases fecal potassium excretion through binding of potassium in the lumen of the gastrointestinal tract. Binding of potassium reduces the concentration of free potassium in the gastrointestinal lumen, resulting in a reduction of serum potassium levels.
Indication	Treatment of hyperkalemia
Comparative agent – Therapeutic interchange?	Sodium polystyrene sulfonate (Kayexalate)
Dosage forms/strengths. Common Dose/sig	Dosage Form: Powder for Oral Suspension Dosage Strengths: 8.4 gm, 16.8 gm, 25.2 gm Recommended Dose: 8.4 grams PO daily; Max Dose of 25.2 grams PO daily
DEA Schedule	None
Date of market availability	January 2016
Similar Medications (Look-Alike Sound-Alike)	None
CLINICAL USE EVALUATION	
Common Adverse Effects	Constipation, hypomagnesemia, diarrhea, nausea, abdominal discomfort, and flatulence
Severe Adverse Effects	Hypomagnesemia
Severe Drug-Drug Interactions	Patiromer may bind to other orally administered medications; separate administration by at least 6 hours
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Serum potassium, serum magnesium
Used in Pediatric Areas	Safety and efficacy in pediatric patients have not been established.
Renal or Hepatic Dosing	No dosage adjustments necessary in renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Contraindicated in patients with a history of hypersensitivity to the product or any product ingredients. • Binding to other orally administered medications – administer other oral medications at least 6 hours before or 6 hours after patiromer • Worsening of gastrointestinal motility – avoid patiromer in patients with severe constipation, bowel obstruction, or impaction. • Hypomagnesemia – patiromer binds to magnesium in the colon. In clinical trials hypomagnesemia was reported in 5.3% of patients treated with patiromer.
Special administration technique or considerations	Administer with food; do not heat patiromer or add to heated foods or liquids. Do not take in the dry powder form. Prepare each dose immediately prior to administration by emptying entire contents of packet into 30 mL of water in a glass or cup. Stir thoroughly. Add an additional 60 mL of water to the glass or cup containing the mixture. Stir the mixture thoroughly; the powder will not dissolve and the mixture will look cloudy. Drink the mixture immediately. If some powder

	remains in the glass after drinking, add more water, stir and drink immediately. Repeat as needed to ensure the entire dose is administered.
Prepared by	Stephanie N. Lind, Pharm.D. Candidate 2016

Trabectedin / Yondelis / Janssen Products	
Generic Name / Brand Name / Company	Trabectedin / Yondelis / Janssen Products
Date of approval	10/23/15
Drug Class (Mechanism of Action if novel agent)	Antineoplastic; alkylating agent. Trabectedin binds guanine residues in the minor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in perturbation of the cell cycle and eventual cell death.
Indication	Treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Sterile lyophilized powder for injection: 1 mg in a single-dose vial Recommended Dose: 1.5 mg/m^2 infused over 24 hours through central venous line every 21 days
DEA Schedule	None
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	None
CLINICAL USE EVALUATION	
Common Adverse Effects	Nausea, fatigue, vomiting, constipation, decreased appetite, diarrhea, peripheral edema, dyspnea, headache, plus common lab abnormalities including neutropenia, increased ALT, thrombocytopenia, anemia, increased AST, and increased creatine phosphokinase
Severe Adverse Effects	Neutropenic sepsis, rhabdomyolysis, hepatotoxicity, cardiomyopathy, extravasation resulting in tissue necrosis, embryofetal toxicity
Severe Drug-Drug Interactions	• Avoid concomitant strong CYP3A inhibitors • Avoid concomitant strong CYP3A inducers
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Assess neutrophils, creatine phosphokinase, AST/ALT, bilirubin prior to each administration of trabectedin
Used in Pediatric Areas	Safety and efficacy in pediatric patients have not been established.
Renal or Hepatic Dosing	There is no recommended dose for patients with serum bilirubin above the upper limit of normal
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Neutropenic Sepsis – 43% of patients in Trial 1 had Grade 3 or 4 neutropenia, median time to first occurrence being 16 days. Assess neutrophil count prior to administration of each dose of trabectedin. • Rhabdomyolysis – elevations of creatine phosphokinase occurred in 32% of patients in trial 1. • Hepatotoxicity – the incidence of Grade 3-4 elevated liver function tests was 35% in Trial 1 and the median time to development of Grade 3-4 elevations in AST/ALT was 29 days. • Cardiomyopathy – including cardiac failure, congestive heart failure, ejection fraction decreased, diastolic dysfunction, or right ventricular dysfunction. • Extravasation Resulting in Tissue Necrosis • Embryofetal toxicity

Special administration technique or considerations	• Premedicate patients with dexamethasone 20 mg IV 30 minutes prior to each dose of trabectedin. • Administer through a central venous line • Consult labeling for dose modifications for laboratory abnormalities or adverse reactions • Using aseptic technique, inject 20 mL of Sterile Water for Injection, USP into the vial. Shake the vial until complete dissolution. Immediately following reconstitution, withdraw the calculated volume of trabectedin and further dilute in 500 mL of 0.9% Sodium Chloride, USP or 5% Dextrose Injection, USP. • Do not mix trabectedin with other drugs.
Prepared by	Stephanie N. Lind, Pharm.D. Candidate 2016

Asfotase alfa / Strensiq / Alexion Pharmaceuticals	
Generic Name / Brand Name / Company	asfotase alfa/ Strensiq/ Alexion Pharmaceuticals
Date of approval	10/23/15
Drug Class (Mechanism of Action if novel agent)	Endocrine and metabolic agents; enzyme replacement. Tissue nonspecific alkaline phosphatase
Indication	Treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP)
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 18 mg/0.45 mL, 28 mg/0.7 mL, 40 mg/mL, 90 mg/0.9 mL solutions in single-use vials Dose: 2 mg/kg subcutaneously 3 times per week or 1 mg/kg subcutaneously 6 times per week
DEA Schedule	None.
Date of market availability	January 2016
Similar Medications (Look-Alike Sound-Alike)	None
CLINICAL USE EVALUATION	
Common Adverse Effects	Injection site reactions, lipodystrophy, ectopic calcifications, and hypersensitivity reactions. <1%: Hypocalcemia, renal stones, chronic hepatitis, decreased vitamin B6
Severe Adverse Effects	None reported.
Severe Drug-Drug Interactions	None reported.
Severe Drug-Food Interactions	None reported.
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Ophthalmology examinations and renal ultrasounds at baseline and periodically throughout treatment.
Used in Pediatric Areas	Safe and effective in pediatric patient populations.
Renal or Hepatic Dosing	None provided.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Hypersensitivity reactions – in clinical trials 1% of patients given asfotase alfa experienced signs and symptoms consistent with anaphylaxis. These reactions occurred approximately 1 minute after injection of the medication. Consider risks and benefits of re-administering following a severe reaction. • Lipodystrophy – reported several months after initiation • Ectopic Calcifications – ectopic calcifications involving the eye and kidneys were reported in 14% of patients in clinical trials. No changes in vision or renal function were reported resulting from these ectopic calcifications. Monitoring is recommended.
Special administration technique or considerations	• Administer within 1 hour of removal of vials from refrigeration

	• Rotate injection site to reduce risk of lipohypertrophy and injection site atrophy. • Do NOT administer injections in areas that are reddened, inflamed, or swollen. • When preparing a volume for injection greater than 1 mL, split the volume equally between two syringes, and administer two injections. Separate injection sites.
Prepared by	Stephanie N. Lind, Pharm.D. Candidate 2016

Talimogene laherparepvec/Imlygic/Amgen Inc.	
Generic Name / Brand Name / Company	Talimogene laherparepvec/Imlygic/Amgen Inc.
Date of approval	10/2015
Drug Class (Mechanism of Action if novel agent)	Antineoplastic; oncolytic viral therapy. Genetically modified herpes simplex virus type 1 designed to replicate within tumors and produce GM-CSF, resulting in cell lysis, tumor rupture, and anti-tumor immune responses.
Indication	Local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 10^6 plaque-forming units per mL and 10^8 plaque-forming units per mL in single use vials Recommended starting dose: 4 mL of 10^6 (1 million) plaque-forming units per mL. Subsequent doses recommended up to 4 mL of 10^8 PFU per mL.
DEA Schedule	None.
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	None
CLINICAL USE EVALUATION	
Common Adverse Effects	Fatigue, chills, pyrexia, nausea, influenza-like illness, and injection site pain
Severe Adverse Effects	Herpetic infection, injection site complications
Severe Drug-Drug Interactions	None reported.
Severe Drug-Food Interactions	None reported.
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	None reported.
Used in Pediatric Areas	Safety and efficacy have not been established.
Renal or Hepatic Dosing	No studies conducted to evaluate pharmacokinetics of talimogene laherparepvec in renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Contraindicated in pregnant patients and immunocompromised patients • Accidental exposure may lead to transmission of talimogene laherparepvec and herpetic infection. All healthcare providers in close contact should avoid direct contact with injected lesions, dressings, or body fluids of treated patients. Providers who are immunocompromised or pregnant should not prepare or administer the product. • Injection site complications – cellulitis and systemic bacterial infection have been reported in clinical studies; consider risk and benefits before continuing treatment in patients with persistent infection or delayed healing. • Immune-mediated events – glomerulonephritis, vasculitis, pneumonitis, worsening psoriasis, and vitiligo have been reported in clinical trials; consider risks and benefits before continuing treatment in patients developing an immune-mediated event
Special administration technique or considerations	• For intralesional injection only.

	• Wear personal protective equipment while preparing or administering • Thaw the total volume of agent required for injection at room temperature (20°-25° C) until liquid (approximately 30 minute). Do not expose the vial to higher temperatures and keep vial in original carton during thawing. • Detachable needle of 18-26 G may be used for solution withdrawal and a detachable needle of 22-26 G may be used for injection. Small unit syringes are recommended for better injection control. • Post injection, apply pressure to injection site for 30 seconds, and then swab injection site(s) with alcohol.
Prepared by	Stephanie N. Lind, Pharm.D. Candidate 2016

Glycopyrrolate Inhalation Powder / Seebri Neohaler / Novartis	
Generic Name / Brand Name / Company	Glycopyrrolate Inhalation Powder / Seebri Neohaler / Novartis
Date of approval	10/29/15
Drug Class (Mechanism of Action if novel agent)	Anticholinergic bronchodilator
Indication	Long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD)
Comparative agent – Therapeutic interchange?	Aclidinium, tiotropium, umeclidinium
Dosage forms/strengths. Common Dose/sig	Inhalation powder capsules containing 15.6 mcg of glycopyrrolate inhalation powder for use with the Neohaler device Dose: Inhale contents of one capsule twice daily
DEA Schedule	Not applicable
Date of market availability	First quarter 2016
Similar Medications (Look-Alike Sound-Alike)	Glycopyrrolate oral solution, tablets, and injection
CLINICAL USE EVALUATION	
Common Adverse Effects	Upper respiratory tract infection and nasopharyngitis
Severe Adverse Effects	Paradoxical bronchospasm, narrow angle glaucoma, urinary retention
Severe Drug-Drug Interactions	Additive anticholinergic effects with other anticholinergic medications
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	None
Used in Pediatric Areas	Not indicated for use in children
Renal or Hepatic Dosing	No dosage necessary in patients with hepatic impairment or mild to moderate renal impairment. Consider potential benefit relative to risks in patients with severe renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Contraindicated in patients with known hypersensitivity to glycopyrrolate or any product ingredients. • Not for use in the treatment of acute symptoms. • Discontinue immediately and start alternative therapy if paradoxical bronchospasm occurs. • Use with caution in narrow-angle glaucoma. • Use with caution in patients with prostatic hyperplasia or bladder neck obstruction.
Special administration technique or considerations	• For oral inhalation only using the Neohaler device • Store capsules in blister, removing only immediately before use
Prepared by	Terri L. Levien, Pharm.D.