Highlights of FDA Activities – 5/1/2018 – 5/31/18

FDA Drug Safety Communications & Drug Information Updates:

Notification of Stolen Octagam 5/8/18
Octapharma USA, FDA, and law enforcement are working to recover cases from two lots of Octagam 10% that were stolen in a truck hijacking in Tennessee on May 3, 2018. The stolen product was from Octagam 10% 2 G (20 mL) lot M801B8541 and Octagam 10% 10 G (100 mL) lot M811A8541. Customers are advised to be alert for tampered product and to ensure products are obtained through the authorized supply chain. Anyone with information about the incident or who has received suspicious or unsolicited offers for Octagam 10% after the date of the theft is asked to contact the FDA Office of Criminal Investigations at 1-800-551-3989.

Gadolinium-based contrast agents (GBCAs): Drug Safety Communication – New Class Warnings 5/16/18
The FDA approved new patient Medication Guides for all GBCAs, in addition to updating prescribing information related to gadolinium retention safety issues. All MRI centers should provide the patient with a Medication Guide prior to the GBCA injection.

Dolutegravir: Drug Safety Communication—Serious Birth Defects 5/18/18
Babies born to women taking dolutegravir during organogenesis may develop neural tube birth defects. Increased risk for these defects was seen in women exposed at the time of becoming pregnant or early in the first trimester in an observational study in Botswana. There are no reported cases of neural tube defects in women taking medication later in pregnancy.

Keytruda (pembrolizumab) & Tecentriq (atezolizumab): Drug Information Update—Efficacy Issue 5/18/18
Clinical trials in urothelial cancer have shown decreased survival with these agents as monotherapy in patients with low PD-L1 expression compared to patients treated with cisplatin or carboplatin-based regimens. Currently both agents are approved for advanced or metastatic urothelial carcinoma in those not eligible for cisplatin-containing regimens, regardless of PD-L1 status. Use of either agent in urothelial cancer should follow the criteria included in the product labeling for use in cisplatin-ineligible patients.

Oral Benzocaine: Drug Safety Communication – Risk of Methemoglobinemia 5/23/18
Over-the-counter oral products containing benzocaine should not be used to treat infants and children younger than 2 years. In addition, benzocaine oral drug products should only be used in adults and children 2 years and older if they contain warnings on the drug label describing the risk of methemoglobinemia. These products carry serious risks and provide little to no benefits for treating oral pain, including sore gums in infants due to teething.

Notification of Stolen Fertility Drugs: Gonal-f RFF Redi-ject and Gonal-f Multi-Dose 5/30/18
There was a theft of 16,000 packages of Gonal-f RFF Redi-ject and Gonal-f Multi-Dose in Italy on May 17, 2018. The products were intended to be shipped to the U.S. Any product with the following reported lot numbers was in the stolen shipment and should not be used: Gonal-f RFF Redi-ject lot BA049137, Gonal-f Multi-dose 1050 U lot BA049037, and 450 U lots BA049143 and BA049040. Anyone who has received suspicious or unsolicited offers for Gonal-f products after the date of the theft is asked to contact the FDA Office of Criminal Investigations at 1-800-551-3989.

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

Piperacillin and Tazobactam for Injection, USP 3.375 g Vials by AuroMedics Pharma: Recall – Vials Contain Particulate Matter. 5/8/18
AuroMedics Pharma recalled two lots of Piperacillin and Tazobactam for injection, USP 3.375g (PP0317061-A, exp. Aug. 2019 and PP0317049-A, exp. Aug. 2019) following detection of glass particulate matter, visible only after reconstitution.

Ampicillin and Sulbactam for Injection USP, 3 g Single –Dose Vials by AuroMedics Pharma: Recall - Presence of Red Particulate Matter. 5/8/18

AuroMedics Pharma recalled two lots of Ampicillin and Sulbactam for injection USP (AS0317041-A, exp. Aug. 2019 and AS0317035-A, exp. Aug. 2019) to the hospital/user level due to customer complaints of the presence of red particulate matter in the product. The particulate matter is believed to be red rubber particles from the manufacturing process of the active ingredients.

Remedy Essentials No-Rinse Cleansing Foam by Medline: Recall – *Burkholderia Cepacia* Contamination 5/10/18

Health professionals and consumers were advised not to use any lot of Medline Remedy Essentials No-Rinse Cleansing Foam. Shadow Holdings dba Bocchi Laboratories recalled two lots of the product due to contamination with the bacteria *B. cepacia*. The CDC reports 10 confirmed cases of infection have been linked to the product.

Homeopathic Products by MBI Distributing: Recall – Manufactured Without Adequate Controls 5/18/18

MBI Distributing recalled all lots of Teething Drops, Nausea Drops, Intestinal Colic Drops, Stomach Calm, Expectorant Cough Syrup, Silver-Zinc Throat Spray, and Argentum Elixir. The products were manufactured without adequate process controls which could lead to variation in strength, quality and purity of the items.

95% Ethyl Alcohol by Ethanol Extraction: Recall – Possible Methanol Contamination 5/24/18

Lake Michigan Distilling Company, LLC, doing business as Ethanol Extraction, recalled its 95% Ethyl Alcohol product due to potential contamination with methanol. The product was sold in plastic bottles from 8 oz to 1 gallon, plus 2.5 gallon and 5 gallon containers, from October 2016 through April 2018 via direct shipment throughout the U.S.

X-Jow and Acne Shave Products by Shadow Holding: Recall – Possible Bacterial Contamination 5/29/18

Shadow Holdings recalled Herb-X Solutions X-Jow Pain Gel (4 oz and 8 oz) and United Exchange Acne Shave Moisturizer (3.3 oz), Acne Shave brand Shave Cream with Acne Shield (5.1 oz), and Acne Shave brand Shave Kit due to potential bacterial contamination. The products were distributed nationwide.

Taytulla (Norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules) by Allergan: Recall – Out of Sequence Capsules 5/29/18

Allergan recalled Taytulla 1 mg/20 mcg, 6x28 physician's sample pack, Lot# 5620706, Exp. May-2019, after reports of four placebo capsules placed in the wrong location in the pack. Specifically, the first four days of therapy had four non-hormonal placebo capsules instead of active capsules.

Fluticasone Propionate Nasal Spray by Apotex Corp.: Recall – Glass Particles 5/31/18

Apotex Corp. recalled Fluticasone Propionate Nasal Spray USP 50 mcg per spray 120 Metered Sprays (Lot NJ4501, Exp. July 2020) due to the presence of small glass particles discovered through a customer complaint.

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***
7K (lot# RO) from Shoreside Enterprises, Inc*	Sexual enhancement	Sildenafil and tadalafil[1]
Best Candy	Energy booster	Nortadalafil, structurally similar to tadalfil[1]
Green Hulu 2 kratom from Badger Botanicals*	Opioid alternative	Salmonella
Green Suma kratom from Badger Botanicals*	Opioid alternative	Salmonella
Poseidon 4500 Extreme 1000 (lot#20117BL) from Shoreside Enterprises, Inc*	Sexual enhancement	Sildenafil and tadalafil[1]
Red Hulu 2 kratom from Badger Botanicals*	Opioid alternative	Salmonella
Red Suma kratom from Badger Botanicals*	Opioid alternative	Salmonella

*Recalled

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

New Product Shortages	***Date Initially Posted***
Lorazepam Injection	5/3/18
Hepatitis B vaccine (recombinant)	5/3/18
Azithromycin (Azasite) Ophthalmic Solution 1%	5/9/18
Epinephrine Injection, Auto-Injector	5/9/18
Fluorescein sodium and benoxinate HCl ophthalmic solution	5/10/18
Isocarboxazid tablets	5/15/18
Zoster vaccine recombinant, adjuvanted (Shingrix, GSK Biologicals)	5/14/18

Product Discontinuations/Withdrawals	***Date Posted***
Isoniazid Tablets (Sandoz): remain available from other manufacturers	5/2/18
Sodium Iodide I 131 capsules and solution (Mallinckrodt Nuclear Medicine LLC): both formulations remain available from at least one other manufacturer	5/3/18
Gabapentin Capsules (Epic Pharmaceuticals): remain available from other manufacturers	5/3/18
Pentoxifylline Extended-Release Tablets (Mylan Pharmaceuticals): remain available from other manufacturers	5/8/18
Morphine Sulfate Extended-Release (Mylan Pharmaceuticals): remain available from other manufacturers	5/8/18
Indomethacin Capsules (Mylan Pharmaceuticals): remain available from other manufacturers	5/8/18
Disulfiram Tablets (Mylan Pharmaceuticals): remain available from other manufactures	5/8/18
Dextroamphetamine Sulfate Extended-Release Capsules (Mylan Pharmaceuticals): remain available from other manufacturers	5/8/18
Clonazepam Tablets (Mylan Pharmaceuticals): remain available from other manufacturers	5/8/18
Didanosine Delayed-Release Capsules (Teva Pharmaceuticals): remain available from other manufacturers	5/9/18
Fluorescein sodium 2.5 mg (0.25%) and benoxinate HCl 4 mg (0.4%) ophthalmic solution (Flurox, OCuSoft): other formulations remain available	5/10/18
Levitra tablets (vardenafil HCL) (Bayer): 2.5 mg tablet strength (NDC 0173-0828-13), other strengths remain available	5/15/18
Lanoxin (digoxin) (Concordia Pharmaceuticals): 187.5 mcg tablets, 100-count bottles (NDC 59212-245-55), generics remain available	5/22/18
Technivie tablets (Ombitasvir; Paritaprevir; Ritonavir) (AbbVie): 212.5 mg/75 mg/50 mg (NDC 0074-3082-28), estimated availability until January 1, 2019	5/22/18
Viekira XR tablets (dasabuvir sodium, ombitasvir, paritaprevir, ritonavir) (AbbVie): estimated availability until January 1, 2019	5/22/18
Hydrochlorothiazide and lisinopril tablets (Mylan): remain available from other manufacturers	5/22/18
Spironolactone tablets (Actavis/Teva): remain available from other manufacturers	5/22/18
Simeprevir 150 mg capsules (Janssen): Alternative antivirals for hepatitis C remain available	5/23/18
Finasteride tablets (Mylan): remain available from other manufacturers	5/23/18
Risperdal (risperidone) tablets (Janssen): generics remain available	5/24/18
Mirtazapine orally disintegrating tablets (Actavis/Teva): remain available from other manufacturers	5/29/18

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Coagulation factor Xa (recombinant), inactivated-zhzo / Andexxa / Portola Pharmaceuticals, Inc.	For reversal of rivaroxaban and apixaban anticoagulation due to life-threatening or uncontrolled bleeding.	5/3/18
Lofexidine HCl / Lucemyra / US WorldMeds LLC	For the mitigation of withdrawal symptoms to facilitate abrupt discontinuation of opioids in adults	5/16/18
Erenumab-aooe / Aimovig / Novartis	Preventative of migraine in adults	5/17/18
Sodium zirconium cyclosilicate / Lokelma / AstraZeneca	Treatment of hyperkalemia	5/18/18
Avatrombopag / Doptelet / Dova Pharmaceuticals	Treatment of thrombocytopenia in adults with chronic liver disease scheduled to undergo medical or dental procedure	5/21/18
Pegvaliase-pqpz / Palynziq / BioMarin Pharmaceutical	Treatment of adults with phenylketonuria (PKU)	5/24/18

New Indications:	***Description***	***Date Approved***
Pregabalin / Lyrica / Pfizer	Adjunctive therapy in the treatment of partial onset seizures in pediatric patients 4 to 16 years of age	5/3/18
Dabrafenib / Tafinlar / Novartis	Use in combination with trametinib (Mekinist) for the treatment of anaplastic thyroid cancer that is unresectable or metastatic with BRAF V600E mutation.	5/4/18
Trametinib / Mekinist / Novartis	Use in combination with dabrafenib (Tafinlar) for the treatment of anaplastic thyroid cancer that is unresectable or metastatic with BRAF V600E mutation.	5/4/18
Daratumumab / Darzalex / Janssen	Use in combination with bortezomib, melphalan, and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant	5/7/18
Brivaracetam / Briviact / UCB	Use in partial-onset seizures in patients 4 years of age and older	5/10/18
Fingolimod / Gilenya / Novartis	Use in the treatment of relapsing forms of multiple sclerosis in patients 10 years of age and older	5/11/18
Emtricitabine; tenofovir disoproxil fumarate / Truvada / Gilead	Use as pre-exposure prophylaxis in at-risk adolescents	5/15/18
Fluticasone furoate / Arnuity Ellipta / GSK	Use in patients 5 years and older with asthma	5/17/18
Denosumab / Prolia / Amgen	Treatment of glucocorticoid-induced osteoporosis in men and women with high fracture risk	5/25/18
Xeljanz / tofacitinib / Pfizer	Use in adults with moderately to severely active ulcerative colitis	5/30/18

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride for oral solution / Plenvu / Salix Pharmaceuticals	Two dose, low volume colonoscopy prep	5/4/18
Epoetin-epbx / Retacrit / Hospira	Biosimilar to Epogen/Procrit (epoetin alfa)	5/15/18
Abiraterone acetate / Yonsa / Sun Pharma	Smaller particle size formulation of abiraterone acetate than Zytiga (Janssen), indicated for the treatment of metastatic castration-resistant prostate cancer	5/22/18
Tacrolimus granules / Prograf / Astellas	Granule formulation for oral suspension for the prevention of rejection in heart, kidney, or liver transplant in pediatric patients	5/24/18
Estradiol vaginal inserts / Imvexxy / TherapeuticsMD	Vaginal inserts for the treatment of moderate to severe dyspareunia	5/29/18
Amlodipine & celecoxib tablet / Consensi / Kitov Pharma	For patients with both hypertension and osteoarthritis	5/31/18

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Coagulation Factor Xa (recombinant), inactivated-zhzo / Andexxa / Portola Pharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Coagulation Factor Xa (recombinant), inactivated-zhzo / Andexxa / Portola Pharmaceuticals, Inc.
Date of approval	5/3/18
Drug Class (Mechanism of Action if novel agent)	Bind and sequester factor Xa inhibitors (rivaroxaban & apixaban), and bind and inhibit Tissue Factor Pathway Inhibitor, thus increasing generation of tissue factor-initiated thrombin.
Indication	Reversal of anticoagulation due to life-threatening or uncontrolled bleeding in patients receiving rivaroxaban or apixaban
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Lyophilized powder 100 mg in a single-use vial. Low dose: 400 mg at 30 mg/min IV bolus, then 4 mg/min for up to 120 minutes IV infusion High dose: 800 mg at 30 mg/min IV bolus, then 8 mg/min for up to 120 minutes IV infusion Low vs High dose is based on mg dose of anti-Xa product used and time since last dose of anti-Xa inhibitor (< 8 hrs vs > 8 hrs)
DEA Schedule	Not applicable
Date of market availability	Limited supplies in June 2018; wider availability anticipated early 2019
Similar Medication Names	Coagulation Factor X Human
Clinical Use Evaluation	
Common Adverse Effects	Urinary tract infections, pneumonia, infusion-related reactions
Severe Adverse Effects	Thromboembolic events
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.	None
Used in Pediatric Areas	Safety and effectiveness have not been established
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Thromboembolic, ischemic, and cardiac events, including death, were observed within 30 days post-administration in 18 % of patients. Restart anticoagulant therapy as soon as medically appropriate.
Special administration technique or considerations	Administer IV using a 0.2 or 0.22 micron in-line polyethersulfone or equivalent low protein-binding filter Initiate IV bolus administration at a target rate of approximately 30 mg/minute. Within 2 minutes for the bolus dose, administer the continuous IV infusion for up to 120 minutes.
Prepared by	Alina Melnychenko
Source	Andexxa (coagulation FXa (recombinant, inactivated-zhzo). [prescribing information]. San Francisco, CA: Portola Pharma, Inc.; 2018

Lofexidine Hydrochloride / Lucemyra / US WorldMeds LLC	
Generic Name / Brand Name / Company	Lofexidine hydrochloride / Lucemyra / US WorldMeds LLC
Date of approval	5/16/18
Drug Class (Mechanism of Action if novel agent)	Central alpha-2 adrenergic agonist that reduces the release of norepinephrine and decreases sympathetic tone
Indication	For the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults
Comparative agent – Therapeutic interchange?	Clonidine (off-label)
Dosage forms/strengths. Common Dose/sig	Tablets: 0.18 mg Dose: 3 tablets orally four times daily at 5-6 hour intervals during peak withdrawal symptoms (generally the first 5 to 7 days after opioid discontinuation). Treatment may be continued up to 14 days guided by symptoms. Taper lofexidine over 2 to 4 days by reducing dose by 1 tablet per dose every 1 to 2 days.
DEA Schedule	Not applicable
Date of market availability	Expected August 2018
Similar Medication Names	Fexofenadine (Fexidine), Lucentis
Clinical Use Evaluation	
Common Adverse Effects	>10%: orthostatic hypotension, bradycardia, hypotension, dizziness, somnolence, sedation, dry mouth
Severe Adverse Effects	QT prolongation, fatal opioid overdose, discontinuation symptoms (hypertension)
Severe Drug-Drug Interactions	CNS depressants: potentiates effects Methadone: QT prolongation, monitor ECG Oral naltrexone: reduced naltrexone efficacy if used within 2 hours CYP2D6 inhibitors (eg, paroxetine): monitor for lofexidine adverse effects
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Assess for hepatic impairment, renal impairment, electrolyte abnormalities prior to initiating
Used in Pediatric Areas	Safety and effectiveness have not been established
Renal or Hepatic Dosing	Reduce dose to 2 tablets 4 times daily in moderate hepatic impairment and mild or moderate renal impairment. Reduce dose to 1 tablet 4 times daily in severe hepatic impairment, severe renal impairment, end-stage renal disease, or in patients on dialysis.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Risk of hypotension, bradycardia, syncope. Risk of QT prolongation Avoid use in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, medications that cause bradycardia, and patients with congenital long QT syndrome.
Special administration technique or considerations	Patients receiving lofexidine as outpatients should be capable of and instructed on self-monitoring for hypotension, orthostasis, and bradycardia.
Prepared by	Amanda Cutler
Source	Lucemyra (lofexidine HCl) [prescribing information]. Louisville, KY: US WorldMeds, LLC.; 2018.

Erenumab-aooe / Aimovig / Novartis and Amgen	
Generic Name / Brand Name / Company	Erenumab-aooe / Aimovig / Novartis and Amgen
Date of approval	5/17/18
Drug Class (Mechanism of Action if novel agent)	Calcitonin gene-related peptide (CGRP) receptor antagonist
Indication	Prevention of migraine in adults
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 70 mg/mL in single-dose prefilled autoinjector or syringe Dose: 70 mg subcutaneously once monthly; some patients may benefit from 140 mg subcutaneously once monthly administered as two consecutive 70 mg injections
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medication Names	Almotriptan, Arava, Eraxis, Erelzi, Erlotinib, Vimizim, Vimpat, Vimovo
Clinical Use Evaluation	
Common Adverse Effects	> 3%: Injection site reactions, constipation
Severe Adverse Effects	None known
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None required
Used in Pediatric Areas	Safety and effectiveness not established
Renal or Hepatic Dosing	Not renally or hepatically eliminated
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	None
Special administration technique or considerations	Allow to sit at room temperature for at least 30 mins protected from direct sunlight before administration; do not shake; inject subcutaneously in abdomen, thigh, or upper arm
Prepared by	Amanda Cutler
Source	Aimovig (erenumab-aooe) injection. [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; 2018.

Sodium zirconium cyclosilicate / Lokelma / AstraZeneca	
Generic Name / Brand Name / Company	Sodium zirconium cyclosilicate / Lokelma / AstraZeneca
Date of approval	5/18/18
Drug Class (Mechanism of Action if novel agent)	Non-absorbed zirconium silicate that captures K+ in exchange for H+ and Na+ ions in the intestines and increases fecal excretion.
Indication	Potassium binder used to treat hyperkalemia in adults
Comparative agent – Therapeutic interchange?	Patiromer sorbitex calcium, sodium polystyrene sulfonate
Dosage forms/strengths. Common Dose/sig	Powder for oral suspension: 5 g or 10 g packet Initial treatment: 10 g three times daily for up to 48 hours Continued treatment: 10 g daily, titrate weekly in 5 g increments Maintenance dose 5-15 g daily
DEA Schedule	Not applicable
Date of market availability	Not known
Similar Medication Names	Aluminum Zirconium, Zirconium Phosphate
Clinical Use Evaluation	
Common Adverse Effects	Mild to moderate edema
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Can cause transient gastric pH increase, which can change pH-dependent solubility of other drugs. Separate administration by at least 2 hours.
Severe Drug-Food Interactions	Adjust dietary sodium as needed (each 5 g dose contains 400 mg of sodium)
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Potassium
Used in Pediatric Areas	Safety and effectiveness not established
Renal or Hepatic Dosing	Not absorbed systemically
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Avoid use in patients with severe constipation, bowel obstruction or impaction and abnormal post-operative bowel motility
Special administration technique or considerations	Mix with 3 tablespoons of water and drink immediately; repeat until no powder remains in the glass. Administer 2 hours before or after other medications.
Prepared by	Alina Melnychenko
Source	Lokelma (sodium zirconium cyclosilicate) for oral suspension [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2018

Avatrombopag / Doptelet / Dova Pharmaceuticals Inc	
Generic Name / Brand Name / Company	Avatrombopag / Doptelet / Dova Pharmaceuticals Inc
Date of approval	5/21/18
Drug Class (Mechanism of Action if novel agent)	Thrombopoietin receptor agonist stimulates proliferation and differentiation of megakaryocytes from bone marrow cells which leads to increased production of platelets
Indication	Thrombocytopenia in chronic liver disease patients about to undergo a procedure
Comparative agent – Therapeutic interchange?	Eltrombopag, MOA is the same, indication is different (chronic immune thrombocytopenia when corticosteroids and splenectomy did not work).
Dosage forms/strengths. Common Dose/sig	Tablets: 20 mg Dose: if platelet count < 40 x 10^9/L: 60 mg (3 tabs) daily X 5 days If platelet count 40 to less than 50 x 10^9/L: 40 mg (2 tabs) daily X 5 days
DEA Schedule	Not applicable
Date of market availability	June 2018
Similar Medication Names	Eltrombopag
Clinical Use Evaluation	
Common Adverse Effects	Pyrexia (10%), abdominal pain (7%), nausea (7%), headache (7%), fatigue (4%), peripheral edema (3%)
Severe Adverse Effects	Hyponatremia, portal vein thrombosis
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Platelet count prior to initiation of therapy and on the day of the procedure
Used in Pediatric Areas	Safety and effectiveness not established
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Do not administer to patients with chronic liver disease in order to normalize platelet count Potential for thromboembolic complications Breastfeeding is not recommended during treatment and for 2 weeks after last dose
Special administration technique or considerations	Begin dosing 10-13 days prior to scheduled procedure Undergo procedure within 5-8 days after last dose Take with food for 5 consecutive days
Prepared by	Alina Melnychenko
Source	Doptelet (avatrombopag) tablets [prescribing information]. Durham, NC: Dova Pharmaceuticals Inc.; 2018

Pegvaliase-pqpz / Palynziq / BioMarin Pharmaceutical	
Generic Name / Brand Name / Company	Pegvaliase-pqpz / Palynziq / BioMarin Pharmaceutical
Date of approval	5/24/18
Drug Class (Mechanism of Action if novel agent)	PEGylated phenylalanine ammonia lyase (PAL) enzyme that converts phenylalanine to ammonia and trans-cinnamic acid to substitute for the deficient phenylalanine hydroxylase (PAH) enzyme activity in patients with phenylketonuria (PKU)
Indication	To reduce blood phenylalanine concentrations in adult patients with PKU who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.
Comparative agent – Therapeutic interchange?	Sapropterin dihydrochloride
Dosage forms/strengths. Common Dose/sig	Injection: 2.5 mg/0.5 mL, 10 mg/0.5 mL, and 20 mg/mL in a single-dose syringe Dose: 2.5 mg once weekly for 4 weeks, titrate step-wise over 5 weeks to achieve a dose of 20 mg subcutaneously once daily
DEA Schedule	Not applicable
Date of market availability	End of June 2018
Similar Medication Names	Pegvisomant
Clinical Use Evaluation	
Common Adverse Effects	>20%: Injection site reactions, arthralgia, hypersensitivity reactions, headache, generalized skin reactions lasting at least 14 days, pruritus, nausea, abdominal pain, oropharyngeal pain, vomiting, cough, diarrhea, and fatigue
Severe Adverse Effects	Anaphylaxis
Severe Drug-Drug Interactions	Other pegylated products or products containing PEG 3350: possible increased risk of hypersensitivity reactions
Severe Drug-Food Interactions	Foods high in phenylalanine
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Obtain blood phenylalanine concentrations before initiating treatment and every 4 weeks until a maintenance dosage is established
Used in Pediatric Areas	Safety and effectiveness not established
Renal or Hepatic Dosing	None ; excretion not studied.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Prescribe auto-injectable epinephrine Monitor for anaphylaxis and hypersensitivity reactions
Special administration technique or considerations	Available only through a restricted program under REMS The initial dose must be administered under the supervision of a healthcare provider prepared to manage anaphylaxis, and the patient must be closely observed for at least 60 minutes following injection. An adult observer should be considered for patients who may need assistance recognizing and managing anaphylaxis; such observer should be present during the injection and for 60 minutes after. Consider premedication with an H1-receptor antagonist, H2-receptor antagonist, and/or antipyretic.
Prepared by	Amanda Cutler
Source	Palynziq (pegvaliase-pqpz) injection [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; 2018.