College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 1/1/2020 – 1/31/2020

FDA Drug Safety Communications & Drug Information Updates:

Belviq, Belviq XR (lorcaserin): Drug Safety Communication - Possible Increased Risk of Cancer 1/14/20
The FDA alerted the public that results from a clinical trial assessing safety show a possible increased risk of cancer with the weight management medicine lorcaserin. At this time, the cause of the cancer is uncertain and the causal relationship with lorcaserin is unproven; however, healthcare providers should consider if the potential benefits of lorcaserin are likely to exceed the potential risk when deciding to initiate or continue patients on lorcaserin. The manufacturer has made the decision to voluntarily withdraw the product from the market.

Clozaril, Fazaclo ODT, Versacloz (clozapine): Drug Safety Communication - FDA Strengthens Warning That Untreated Constipation Can Lead to Serious Bowel Problems 1/28/20
FDA is strengthening an existing warning that constipation caused by the schizophrenia medicine clozapine (Clozaril, Fazaclo ODT, Versacloz, generics) can, uncommonly, progress to serious bowel complications leading to hospitalization or death. Evaluate bowel function before initiating clozapine, avoid concurrent treatment with other anticholinergic medications that can cause gastrointestinal hypomotility, monitor patients for symptoms of gastrointestinal hypomotility, and consider prophylactic laxative treatment in patients with a history of constipation or bowel obstruction.

FDA Launches Mobile-Friendly Database to Improve Access to Information on HIV Drugs 1/29/2020
The FDA announced the launch of an interactive, mobile friendly database that will offer information about antiretrovirals (ARV) eligible for purchase under the President's Emergency Plan for AIDS Relief (PEPFAR) program. The PEPFAR program is designed to enhance the amount and availability of information and data provided on each ARV drug to the public and health care providers.

FDA requests withdrawal of bacitracin for injection from market 1/31/20
The FDA requested that all current manufacturers of bacitracin for injection voluntarily withdraw their product from the market. Bacitracin for injection is currently FDA-approved to treat infants with pneumonia and empyema caused by susceptible staphylococci; however, health care professionals no longer use bacitracin for injection to treat this condition because other effective FDA-approved treatments are available that do not have the same serious risks, including nephrotoxicity, anaphylactic reactions, and the need for repeated intramuscular injections.

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

Mirtazapine Tablets, Aurobindo Pharma USA, Inc.: Recall - Label Error on Declared Strength 1/2/20
Aurobindo Pharma USA, Inc. recalled lot number 03119002A3 of mirtazapine tablets to the consumer level due to a label error on declared strength; bottles labeled as mirtazapine 7.5 mg may contain 15 mg tablets.

Ranitidine Hydrochloride Capsules 150 mg and 300 mg, Appco Pharma LLC.: Recall - Elevated NDMA 1/8/20
Appco Pharma LLC recalled all quantities and lots of ranitidine hydrochloride capsules to the consumer level because of the presence or potential presence of N-nitrosodimethylamine (NDMA) levels above the acceptable daily intake levels established by the FDA, based on FDA-validated tests.

Nizatidine Capsules, USP, Mylan: Recall - Trace Amounts of NDMA 1/8/20
Mylan Pharmaceuticals recalled to the consumer level three lots of nizatidine capsules, USP 150 mg and 300 mg strengths (Lot #s 3086746, 3082876, 3082877) due to detected trace amounts of an impurity NDMA contained in the active ingredient manufactured by Solara Active Pharma Sciences Limited.

Ranitidine Tablets, Denton Pharma, Inc. dba Northwind Pharmaceuticals: Recall - Possible NDMA 1/8/20
Denton Pharma, Inc. dba Northwind Pharmaceuticals, recalled all lots of ranitidine tablets, 150 mg and 300 mg, to the consumer level due to the potential presence of NDMA impurity.

Lamotrigine Tablets USP, Taro Pharmaceuticals U.S.A., Inc.: Recall – Cross-contamination 1/10/20
Taro Pharmaceuticals U.S.A., Inc. recalled one lot of lamotrigine 100 mg tablets (Lot # 331771, expiration date June 2021) in 100 count bottles, NDC 51672-4131-1 to the consumer level. This single lot was found to have been cross-contaminated with a small amount of enalapril maleate used to manufacture another product at the same facility.

FUSION IV Pharmaceuticals, Inc (AXIA Pharmaceutical): Recall - Lack of Assurance of Sterility 1/16/20
FUSION IV Pharmaceuticals, Inc doing business as AXIA Pharmaceutical recalled all sterile drug products, to the user level, due to a lack of assurance of sterility.

Rompe Pecho EX, Rompe Pecho CF, and Rompe Pecho MAX, Efficient Laboratories, Inc.: Recall - Microbial Contamination 1/31/20
Efficient Laboratories, Inc. recalled one lot each of Rompe Pecho EX (lot 19F332, exp June 2022), Rompe Pecho CF (lot 19H359, exp August 2022), and Rompe Pecho MAX (lot 19B42, exp February 2022) cough and cold liquids due microbial contamination.

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***
All products from ABH Nature's Products, ABH Pharma, and Stocknutra.com*	Dietary supplements	Violations of current good manufacturing practice regulations
Nopalina Flax Seed Fiber (powder & capsule)*	Weight management, blood sugar, cholesterol, and bowel regularity	Salmonella in the senna ingredient

*recalled

New Product Shortages	***Date Initially Posted***
Ranitidine tablets/capsules	1/7/20

Product Discontinuations/Withdrawals	***Date Posted***
Anastrozole tablets (Apotex); remains available from other manufacturers	1/21/20
Argatroban Injection 250 mg single dose vial (Novartis); remains available from other manufacturers	1/15/20
Bethanechol Chloride Tablets (Teva); remains available from other manufacturers	1/13/20
Dutasteride Capsules (Apotex); remains available from other manufacturers	1/7/20
Gatifloxacin ophthalmic solution (Mylan Pharmaceuticals); remains available from other manufacturers	1/27/20
Gemcitabine Hydrochloride Injection (Apotex); remains available from other manufacturers	1/8/20
Gemcitabine Hydrochloride Injection (Teva); remains available from other manufacturers	1/7/20
Levocetirizine Dihydrochloride tablets (Apotex); remains available from other manufacturers	1/21/20
Methscopolamine Bromide tablets (Par Pharmaceutical); remains available from other manufacturers	1/27/20
Nevirapine Extended Release Tablets (Sandoz); remains available from other manufacturers	1/24/20
Pramipexole Dihydrochloride Extended Release 4.5 mg Tablets (Endo Pharmaceuticals); remains available from other manufacturers	1/27/20
Sodium Lactate Injection, USP (Hospira, Inc)	1/9/20
Temozolomide capsules (Temodar, Merck Sharp & Dohme Corp); generics remain available	1/23/20

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Avapritinib / Ayvakit / Blueprint Medicines Corporation	Kinase inhibitor for treatment of adults with gastrointestinal stromal tumor with a PDGFRA exon 18 mutation	1/9/20
Teprotumumab-trbw / Tepezza/ Horizon Therapeutics USA, Inc.	Insulin-like growth factor-1 receptor inhibitor for the treatment of thyroid eye disease	1/21/20
Tazemetostat / Tazverik / Epizyme Inc.	Methyltransferase inhibitor for the treatment of patients 16 years and older with advanced epithelioid sarcoma	1/23/20
Peanut (Arachis hypogaea) allergen powder-dnfp / Palforzia / Aimmune Therapeutics, Inc.	Oral immunotherapy for mitigation of allergic reactions that may occur with accidental exposure to peanut in patients 4 years and older with confirmed peanut allergy	1/31/20

New Indications:	***Description***	***Date Approved***
Pembrolizumab / Keytruda / Merck & Co., Inc..	Treatment of patients with BCG-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy	1/8/20
Infliximab-qbtx / Ixifi / Pfizer	Use for reducing signs and symptoms and inducing and maintaining clinical remission in patients 6 years and older with moderately to severely active ulcerative colitis with inadequate response to conventional therapy	1/16/20
Semaglutide injection / Ozempic / Novo Nordisk Inc.	Reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease	1/16/20
Vigabatrin / Sabril / Lundbeck Pharmaceuticals	Indication expanded for tablets and powder for oral solution for use in patients 2 years and older with refractory complex partial seizures	1/24/20
Canaglliflozin and metformin HCl / Invokamet and Invokamet XR / Janssen Pharmaceuticals	To reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day	1/27/20
Fidaxomicin / Dificid/ Merck & Co., Inc.	Use in pediatric patients 6 months of age or older for the treatment of *Clostridioides difficile* associated diarrhea	1/24/20

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Cocaine HCl 4% nasal solution / Numbrino / Cody Laboratories, Inc	Nasal solution 4%: 40 mg/mL in 4 mL and 10 mL bottles; local anesthesia of the mucous membranes for diagnostic procedures and surgeries on or through the nasal cavities of adults	1/10/20
Diazepam nasal spray / Valtoco / Neurelis Inc.	Nasal spray: 5 mg, 7 mg, or 10 mg in 0.1 mL (see attached drug summary)	1/10/20
Ferric derisomaltose / Monoferric / Pharmacosmos Therapeutics, Inc.	Injection: 100 mg, 500 mg, 1000 mg; Administered as an intravenous infusion as a single dose (see attached drug summary)	1/16/20
Fidaxomicin / Dificid / Merck & Co., Inc.	Granules for oral suspension: 40 mg/mL supplied in a 150 mL glass bottle; after reconstitution total suspension volume is 136 mL	1/24/20

Fremanezumab-vfrm injection / Ajovy / Teva Pharmaceuticals USA	Autoinjector: 225 mg/1.5 mL for subcutaneous administration; calcitonin gene-related peptide antagonist indicated for migraine prevention	1/27/20
Empagliflozin, linagliptin, and metformin / Trijardy XR / Boehringer Ingelheim Pharmaceuticals	Extended-release tablets: combination indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	1/27/20
Octreotide acetate injection / Bynfezia Pen / Sun Pharmaceutical	Injection: 2500 mcg/mL as 2.8 mL single-patient-use pen; somatostatin analog for use in acromegaly, diarrhea/flushing associated with metastatic carcinoid tumors, and diarrhea associated with vasoactive intestinal peptide tumors	1/28/20
Influenza A (H5N1) monovalent vaccine, adjuvanted / Audenz / Seqirus	For immunization for the prevention of influenza A H5N1 in persons 6 months and older; to be included in US Strategic National Stockpile.	1/31/20

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Avapritinib / Ayvakit / Blueprint Medicines Corporation	
Generic Name / Brand Name / Company	Avapritinib / Ayvakit / Blueprint Medicines Corporation
Date of approval	1/9/20
Drug Class (Mechanism of Action if novel agent)	Tyrosine kinase inhibitor
Indication	Indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.
Comparative agent – Therapeutic interchange?	Imatinib, sunitinib, regorafenib, nilotinib, pazopanib, dasatinib
Dosage forms/strengths	Tablets: 100 mg, 200 mg, and 300 mg
Common Dose/sig	The recommended dose is 300 mg once daily. Dose modifications are recommended for adverse reactions.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Avastin
Clinical Use Evaluation	
Common Adverse Effects	≥20%: edema, nausea, fatigue/asthenia, cognitive impairment, vomiting, decreased appetite, diarrhea, hair color changes, increased lacrimation, abdominal pain, constipation, rash and dizziness
Severe Adverse Effects	Serious adverse reactions occurring in ≥1% of patients who received avapritinib were anemia (9%), abdominal pain (3%), intracranial hemorrhage (3%), pleural effusion (3%), sepsis (3%), gastrointestinal hemorrhage (2%), vomiting (2%), acute kidney injury (2%), pneumonia (1%) and tumor hemorrhage (1%). Fatal adverse reactions occurred in

	3.4% of patients. Fatal adverse reactions that occurred in more than one patient were sepsis and tumor hemorrhage (1% each).
Severe Drug-Drug Interactions	Strong and Moderate CYP3A Inhibitors: avoid coadministration of avapritinib with strong and moderate CYP3A inhibitors. If coadministration with a moderate inhibitor cannot be avoided, reduce the dose of avapritinib. Strong and Moderate CYP3A Inducers: avoid coadministration of avapritinib with strong and moderate CYP3A inducers.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Test for PDGFRA exon 18 mutation and PDGFRA D842V mutations
Used in Pediatric Areas	Safety and effectiveness in pediatric patients have not been established
Renal or Hepatic Dosing	Renal Impairment: No dose adjustment is recommended for patients with mild or moderate renal impairment [CLcr 30 to 89 mL/min]. The recommended dose of avapritinib has not been established for patients with severe renal impairment (CLcr 15 to 29 mL/min) or end-stage renal disease (CLcr <15 mL/min). Hepatic Impairment: No dose adjustment is recommended for patients with mild or moderate hepatic impairment. The recommended dose has not been established for patients with severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings/Precautions • Intracranial hemorrhage: withhold avapritinib for grade 1 or 2 reactions until resolution and then resume at a reduced dose. Permanently discontinue for recurrent grade 1 or 2 reactions or first occurrence of grade 3 or 4 reactions. • Central nervous system effects: CNS adverse reactions include cognitive impairment, dizziness, sleep disorders, mood disorders, speech disorders, and hallucinations. Depending on the severity, continue avapritinib at same dose, withhold dose and then resume at same or reduced dose upon improvement, or permanently discontinue. • Embryo-fetal toxicity: can cause fetal harm. Advise females and males of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 weeks after the last dose.
Special administration technique or considerations	Take tablet on an empty stomach, at least 1 hour before and 2 hours after a meal. Continue treatment until disease progression or unacceptable toxicity. Do not make up for a missed dose within 8 hours of the next scheduled dose. Do not redose if vomiting occurs.
Prepared by	Estera Pruteanu
Source	Ayvakit (avapritinib) [prescribing information]. Cambridge, MA: Blueprint Medicines Corporation; January 2020.

Teprotumumab-trbw / Tepezza / Horizon Therapeutics USA, Inc.	
Generic Name / Brand Name / Company	Teprotumumab-trbw / Tepezza / Horizon Therapeutics USA, Inc.
Date of approval	1/21/20
Drug Class (Mechanism of Action if novel agent)	Fully human monoclonal antibody, insulin-like growth factor-1 receptor (IGF-1R) inhibitor
Indication	Indicated for the treatment of active thyroid eye disease
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	500 mg lyophilized powder in a single-dose vial for reconstitution
Common Dose/sig	Initiate dosing with 10 mg/kg for first infusion, followed by 20 mg/kg

	every 3 weeks for 7 additional infusions.
DEA Schedule	None
Date of market availability	March 2020
Similar Medication Names	Teplizumab
Clinical Use Evaluation	
Common Adverse Effects	> 5%: muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dry skin, dysgeusia and headache
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	No studies evaluating the drug-drug interaction potential have been conducted
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Blood glucose
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild to moderate renal impairment; no data in severe renal impairment or in hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings and Precautions: • Infusion reactions: if an infusion reaction occurs, interrupt or slow the rate of infusion and use appropriate medical management (corticosteroids and antihistamines). May occur during or within 1.5 hours after infusion. In patients experiencing infusion reactions, can pre-medicate with an antihistamine, antipyretic, or corticosteroid, and/or administer subsequent infusions at a slower infusion rate. • Exacerbation of preexisting inflammatory bowel disease (IBD): monitor patients with preexisting IBD for flare of disease; discontinue teprotumumab-trbw if IBD worsens. • Hyperglycemia: monitor glucose levels in all patients; treat hyperglycemia with glycemic control medications. Patients with pre-existing diabetes should be under glycemic control prior to receiving teprotumumab-trbw. • May cause fetal harm. Females of reproductive potential should be advised to use effective contraception prior to initiation, during treatment, and for 6 months after the last dose.
Special administration technique or considerations	Administer diluted teprotumumab-trbw by intravenous infusion over 90 minutes for the first two infusions. Subsequent infusions can be reduced to 60 minutes if well tolerated.
Prepared by	Estera Pruteanu
Source	Tepezza (teprotumumab-trbw) [prescribing information]. Lake Forest, IL: Horizon Therapeutics USA; Revised January 2020

Tazemetostat / Tazverik / Epizyme Inc	
Generic Name / Brand Name / Company	Tazemetostat / Tazverik / Epizyme Inc
Date of approval	1/23/20
Drug Class (Mechanism of Action if novel agent)	Blocks activity of EZH2 methyltransferase
Indication	Indicated for the treatment of adults and pediatric patients aged 16 years or older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Tablet: 200 mg
Common Dose/sig	800 mg orally twice daily; dose modifications for adverse reactions.

DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Tazicef, Tazorac
Clinical Use Evaluation	
Common Adverse Effects	≥ 20%: pain, fatigue, nausea, decreased appetite, vomiting, constipation
Severe Adverse Effects	Anemia, pain, decreased appetite, weight loss, hemorrhage, decreased hemoglobin, decreased lymphocytes, increased ALT, increased AST
Severe Drug-Drug Interactions	Avoid coadministrations with strong CYP3A inhibitors. If coadministration with a moderate CYP3A inhibitor cannot be avoided, decrease tazemetostat dose. Coadministration of tazemetostat with CYP3A substrates (including hormonal contraceptives) can results in decreased concentration and reduced efficacy of CYP3A substrates.
Severe Drug-Food Interactions	Grapefruit and grapefruit juice - avoid
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Complete blood count, blood chemistry
Used in Pediatric Areas	Safety and efficacy established in patients 16 years and older.
Renal or Hepatic Dosing	No dose adjustment is recommended for patients with renal impairment or for mild hepatic impairment. It has not been studied in patients with moderate to severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Secondary malignancies (myelodysplastic syndrome or acute myeloid leukemia) occurred in 0.6% of patients, one pediatric patient developed T-cell lymphoblastic lymphoma. Embryo-Fetal Toxicity: tazemetostat can cause fetal harm when administered to pregnant women. Advise females of reproductive potential to use effective contraception during treatment and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose.
Special administration technique or considerations	Can be taken with or without food; tablets should be swallowed whole. Additional dose should not be taken if a dose is missed or if vomiting occurs.
Prepared by	Racheal Fitzgerald
Source	Tazverik (tazemetostat) [prescribing information]. Cambridge, MA: Epizyme Inc; January 2020.

Ferric derisomaltose / Monoferric / Pharmacosmos Therapeutics, Inc.	
Generic Name / Brand Name / Company	Ferric derisomaltose / Monoferric / Pharmacosmos Therapeutics, Inc.
Date of approval	1/29/20
Drug Class (Mechanism of Action if novel agent)	Iron replacement
Indication	Iron deficiency anemia in adult patients who have an intolerance to oral iron or have had unsatisfactory response to oral iron, or who have non-hemodialysis dependent chronic kidney disease.
Comparative agent – Therapeutic interchange?	Ferric carboxymaltose, ferumoxytol, iron dextran, iron sucrose, sodium ferric gluconate complex
Dosage forms/strengths	Injection: 1,000 mg iron /10 mL (100 mg/mL) single-dose vial Injection, 500 mg iron/5 mL (100 mg/mL) single-dose vial, and 100 mg iron/mL single-dose vial

Common Dose/sig	For patients weighing 50 kg or more, administer 1000 mg by intravenous infusion over at least 20 minutes as a single dose. Repeat dose if iron deficiency anemia reoccurs. For patients weighing less than 50 kg, administer as 20 mg/kg actual body weight by intravenous infusion over at least 20 minutes as a single dose. Repeat dose if iron deficiency anemia reoccurs.
DEA Schedule	None
Date of market availability	Not announced
Similar Medication Names	Ferric carboxymaltose
Clinical Use Evaluation	
Common Adverse Effects	≥1%: rash and nausea
Severe Adverse Effects	Hypersensitivity reaction
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.	Hematocrit, hemoglobin, serum ferritin, MCV, TIBC, percent saturation of transferrin
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No recommendations for adjustment in renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindication: serious hypersensitivity to ferric derisomaltose or any of the product components. Warnings: Monitor patients for signs and symptoms of hypersensitivity during and after administration for at least 30 minutes and until clinically stable following completion of the infusion. Do not administer to patients with iron overload.
Special administration technique or considerations	Administer the prepared solution via intravenous infusion over at least 20 minutes. Monitor for signs and symptoms of hypersensitivity during and for 30 minutes after infusion. Only administer when personnel and therapies are immediately available to treat serious hypersensitivity reactions. Extravasation of ferric derisomaltose may cause brown discoloration at the extravasation site which may be long lasting. Monitor for extravasation. If extravasation occurs, discontinue administration at that site.
Prepared by	Racheal Fitzgerald
Source	Monoferric (ferric derisomaltose)[prescribing information]. Holbaek, Denmark: Pharmacosmos A/S; January 2020.

Diazepam nasal spray / Valtoco / Neurelis Inc.	
Generic Name / Brand Name / Company	Diazepam nasal spray / Valtoco / Neurelis Inc.
Date of approval	1/10/20
Drug Class (Mechanism of Action if novel agent)	Benzodiazepine
Indication	Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients 6 years and older with epilepsy
Comparative agent – Therapeutic interchange?	Diazepam rectal gel
Dosage forms/strengths	Nasal spray: 5 mg, 7.5 mg, or 10 mg in 0.1 mL single dose ready-to-use spray device.
Common Dose/sig	5 to 10 mg administered as a single spray intranasally into one nostril, or 15 to 20 mg administered as one spray in each nostril. Dose dependent on

	patient's age and weight. A second dose may be administered at least 4 hours after the initial dose. No more than 2 doses should be used to treat a single episode.
DEA Schedule	IV
Date of market availability	March 2020
Similar Medication Names	Valtrex
Clinical Use Evaluation	
Common Adverse Effects	>4%: somnolence, headache, nasal discomfort
Severe Adverse Effects	Hypoventilation, rash
Severe Drug-Drug Interactions	CNS depressants, inhibitors of CYP2C19 and CYP3A4: concomitant use may increase adverse reactions. Inducers of CYP2C19 and CYP3A4 could reduce diazepam effectiveness.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Safety and efficacy established in patients 6 years and older. Avoid use in neonates or infants.
Renal or Hepatic Dosing	No adjustments recommended; pharmacokinetics following nasal administration not studied in subjects with renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: known hypersensitivity to diazepam or acute narrow angle glaucoma Warnings: Concomitant use with opioids may result in profound sedation, respiratory depression, or death. CNS depression, suicidal behavior and ideation Open-angle glaucoma: use only if receiving appropriate therapy Contains benzyl alcohol, which can cause serious adverse reactions in neonates and infants.
Special administration technique or considerations	Two devices are necessary to administer a 15 mg or 20 mg dose. Do not test or prime or attempt to use a single device for more than one administration.
Prepared by	Terri Levien, PharmD
Source	Valtoco (diazepam) nasal spray [prescribing information]. San Diego, CA: Neurelis, Inc.; January 2020.

Peanut (Arachis hypogaea) allergen powder-dnfp / Palforzia / Aimmune Therapeutics, Inc.	
Generic Name / Brand Name / Company	Peanut (Arachis hypogaea) allergen powder-dnfp / Palforzia / Aimmune Therapeutics, Inc.
Date of approval	1/31/20
Drug Class (Mechanism of Action if novel agent)	Immunotherapy
Indication	Mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients with confirmed peanut allergy
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Powder for oral administration supplied in 0.5 mg, 1 mg, 10 mg, 20 mg, and 100 mg capsules and 300 mg sachets
Common Dose/sig	Following single day dose escalation and dose titration from 3 mg to 300 mg over 22 weeks, the maintenance dose is 300 mg orally once daily.
DEA Schedule	None
Date of market availability	Second half of 2020; will be available only through a REMS program
Similar Medication Names	Palifermin
Clinical Use Evaluation	

Common Adverse Effects	>5%: abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, ear pruritus
Severe Adverse Effects	Anaphylaxis, eosinophilic gastrointestinal disease
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known; continue a peanut-avoidant diet
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Evaluated in patients 4 years and older
Renal or Hepatic Dosing	No dosage adjustments recommended
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: uncontrolled asthma, history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease Warnings: Anaphylaxis: prescribe injectable epinephrine Asthma: ensure asthma is under control prior to initiating therapy Eosinophilic gastrointestinal disease: discontinue immunotherapy and consider this diagnosis in patients with severe or persistent gastrointestinal symptoms. Gastrointestinal adverse reactions: pain, vomiting, nausea, oral pruritus, and oral paresthesia were commonly reported; dose modification should be considered.
Special administration technique or considerations	Capsules or sachet should be opened, and entire contents emptied onto a few spoonfuls of refrigerated or room temperature semisolid food (eg, applesauce, yogurt, pudding). The powder should be mixed into the food and the entire volume of the prepared mixture promptly consumed. Wash hands immediately after handling the capsules or sachets. Patient must not swallow capsules or inhale powder. Initial dose escalation is administered on a single day under the supervision of a health care professional in a health care setting. During dose escalation, each dose should be separated by an observation of 20 to 30 minutes, with an observation period of at least 60 minutes after the last dose. The first dose of each new Up-Dosing level is administered under the supervision of a health care professional in a health care setting. Patients should be observed at least 60 minutes after administration of the first dose. If tolerated, the patient may continue that dose level at home, administering each dose with a meal at approximately the same time each day, preferably in the evening. Patients should delay dosing after strenuous exercise until signs of hypermetabolic state (eg, flushing, sweating, rapid breathing, rapid heart rate) have subsided, and avoid hot showers or baths immediately prior to or within 3 hours after consuming a dose.
Prepared by	Terri Levien, PharmD
Source	Palforzia (Peanut [Arachis hypogaea] allergen powder-dnfp) [prescribing information]. Brisbane, CA: Aimmune Therapeutics, Inc.; January 2020.