WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 3/1/22 – 3/31/22

FDA Drug Safety Communications & Drug Information Updates:

At-Home Covid-19 Tests: Drug Safety Communication – Proper Use and Storage 3/18/22
The FDA alerted people that there is a potential for harm if FDA authorized at-home COVID-19 tests are not used according to the manufacturer's directions. Incorrect use of can cause harm if, for example, the liquid solutions in contact the skin or eyes or if the parts of the test are swallowed. The FDA is also reminding people to keep the tests out of reach from children and pets.

Prefilled Saline Flush Syringe Conservation Strategies 3/21/22
The FDA issued a letter containing recommendations for responding to the current shortage of prefilled saline lock/flush syringes. Strategies may include use of single-dose vials of preservative-free, sterile, 0.9% sodium chloride if prefilled syringes are not available, as well as use of heparin lock flush syringes when medically appropriate. Expired prefilled syringes should not be used.

Sotrovimab Emergency Use Authorization Updated 3/25/22 & 3/30/22
The FDA updated the sotrovimab EUA due to increasing prevalence of the BA.2 subvariant to no longer authorize use in Health and Human Services (HHS) region 1 (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), region 2 (New Jersey, New York, Puerto Rico, and the Virgin Islands), region 5 (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin), region 9 (Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Republic of Palau), and region 10 (Alaska, Idaho, Oregon, and Washington). The EUA was further updated in April to no longer authorize sotrovimab for use in the US due to rising rates of BA.2 infection.

Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals 3/29/22
The FDA authorized a second booster dose of either the Pfizer-BioNTech or the Moderna COVID-19 vaccines for people 50 years and older and certain immunocompromised individuals at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine. More information can be found at the FDA website.

Thyroid Monitoring in Babies and Young Children After Iodine-Containing Contrast Media 3/30/22
The FDA recommends that newborns and children through 3 years old have thyroid monitoring within 3 weeks after receiving contrast media containing iodine for medical imaging procedures. An FDA review showed that underactive thyroid or a temporary decrease in thyroid hormone levels were uncommon, but given the importance of early identification and treatment of thyroid problems routine monitoring is recommended.

Compounded products from North American Custom Laboratories LLC, FarmaKeio Superior Custom Compounding – Warning – Lack of Sterility Assurance 3/30/22
The FDA warned patients and health care professionals to not use compounded products intended to be sterile from North American Custom Laboratories LLC, doing business as FarmaKeio Superior Custom Compounding, Richardson TX, following inspection of the facility.

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

0.9% Sodium Chloride for Injection USP 250 mL in Excel by B. Braun: Recall - Fluid Leakage/Low Volume 3/4/22
B. Braun Medical Inc. recalled five lots of 0.9% Sodium Chloride for Injection 250 mL in Excel to the hospital/user level due to fluid leakage or low fill volume. Lot numbers affected by the recall are J1E086, J1E204, J1E213, J1H137, and J1H138.

Hand Sanitizer Isopropyl Alcohol Antiseptic 75% by Tennessee Technical Coatings Corp: Recall – Presence of Methanol 3/7/22

Tennessee Technical Coatings Corp. recalled all lots of Hand Sanitizer Isopropyl Alcohol Antiseptic 75% (NDC: 76921-000-01) to the consumer level following an FDA analysis that found the product to contain methanol.

Sodium Acetate Injection, USP by Fresenius Kabi: Recall – Presence of Particulate Matter 3/7/22

Fresenius Kabi USA recalled seven lots of Sodium Acetate Injection, USP, 400 mEq/100 mL (4 mEq/mL), 100 mL fill in a 100 mL vial (NDC: 63323-032-00) to the user level due to the presence of particulate matter in reserve and stability sample vials. Analyses have determined the presence of particulates composed of carbon and oxygen with varying amounts of iron and trace amounts of sodium, silicon, chromium, aluminum and cellulose. More information including the affected batch numbers and expiration dates can be found at the FDA website.

Similac PM 60/40 Powder Infant Formula by Abbott: Recall – *Cronobacter sakazakii* and *Salmonella Newport* contamination 3/7/22

Abbott expanded the recall of lots of Similac, Alimentum, and EleCare powder formula from 2/17/22 to include one lot of Similac PM 60/40 (lot #27032K80 (can)/lot #27032K800 (case)) following the death of an infant who tested positive for *Cronobacter sakazakii* and had consumed Similac from this lot. At this time no distributed products or retained samples from this lot have tested positive for *Cronobacter sakazakii*. The investigation is ongoing.

Seven Compounded Products by Olympia Pharmacy: Recall – Out of Specification 3/10/22

Olympia Pharmacy, Orlando, FL recalled 11 specific lots of Trimix Formulas F-9, T-105, SB-4, Sermorelin, Sincalide, Hydroxocobalamin, and NAD (compounded injectables) because they were found to be out of specification. For more information, click here.

Infusion Pumps from Baxter: Recall – Alarm Failure 3/14/22

Baxter recalled SIGMA Spectrum infusion Pumps with Master Drug Library (Version 8) and Spectrum IQ Infusion Systems with Dose IQ Safety Software (Version 9) due to the risk of not alarming for repeated upstream occlusion events. Baxter has received 51 reports of serious injuries and three reports of patient deaths over 5 years that are potentially associated with this issue. Clinicians may continue to use the pumps following the instructions and troubleshooting section in the Operator's Manual.

COVID-19 Antigen Tests (Nasal/Saliva) and COVID-19 IgG/IgM Antibody Tests by LuSys Laboratories: Recall – Not Authorized by the FDA 3/14/22

LuSys Laboratories is recalling these tests because they do not have an EUA, 510(k), or PMA and cannot be legally marketed or distributed in the United States. LuSys Laboratories did not provide appropriate validation data to show that the tests can perform accurately. There is a risk of false negative, false positive, and misinterpretation of results. It is recommended to stop using these tests immediately.

SD Biosensor STANDARD Q COVID-19 Ag Home Tests: Recall – Not Authorized by the FDA 3/17/22

SD Biosensor recalled STANDARD Q COVID-19 Ag Home Test. This test, packaged in a white and magenta box and has not been authorized, cleared, or approved by the FDA for distribution in the United States. There is a concern for false results when using this test. The recall follows a FDA Safety Communication regarding this test on 3/1/22.

Celltrion DiaTrust COVID-19 Tests: Recall – False Positive Results 3/17/22

Celltrion USA has recalled Lot COVGCCM0008 of the DiaTrust COVID-19 Ag Rapid Test due to a high number of false positive results. In addition, labeling includes a shelf-life of 18 months, which is beyond the authorization specified in the FDA EUA. The recall follows a FDA Safety Communication regarding this test on 3/1/22.

Jergens Ultra Healing Moisturizer by Kao USA: Recall – Presence of *Pluralibacter gergoviae* 3/18/22

Kao USA recalled Jergens Ultra Healing Moisturizer 3 oz and 10 oz product due to presence of *Pluralibacter gergoviae*. A list of recalled lots can be found on the FDA site.

Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing) by ACON: Recall – Not Authorized 3/21/22
ACON Laboratories recalled the Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing) from ACON Biotech. This test is packaged in a dark blue box and has not been authorized, cleared, or approved by the FDA for distribution of use in the United States. The Flowflex COVID-19 Antigen Home Test from ACON Laboratories remains available and is authorized for use in the United States. The recall follows a FDA Safety Communication regarding this test on 3/1/22.

Symjepi (epinephrine) Injection by Adamis Pharmaceuticals: Recall – Potential Clogging of Needle 3/22/22
Adamis Pharmaceuticals Corporation recalled certain lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes to the consumer level due to the potential clogging of the needle preventing the dispensing of epinephrine. The affected lot numbers and expiration dates can be found at the FDA website.

Accuretic (quinapril/hydrochlorothiazide), Quinapril and Hydrochlorothiazide Tablets, and Quinapril/Hydrochlorothiazide Tablets by Pfizer: Recall – Nitrosamine Content 3/22/22
Pfizer recalled Accuretic (quinapril HCl/hydrochlorothiazide) tablets distributed by Pfizer as well as two authorized generics distributed by Greenstone (quinapril and hydrochlorothiazide and quinapril/ hydrochlorothiazide) to the patient level due to the presence of a nitrosamine above the acceptable level. Affected lot numbers and expiration dates can be found at the FDA website.

Orphenadrine Citrate 100 mg Extended-Release Tablets by Sandoz: Recall – Nitrosamine Impurity 3/22/22
Sandoz recalled 13 lots of orphenadrine citrate 100 mg extended-release tablets to the consumer level due to the presence of a nitrosamine impurity above acceptable limit. Affected lot numbers and expiration dates can be found at the FDA website.

Unit Dose Cups by Major Pharmaceuticals: Recall – Microbial Contamination 3/24/22
Plastikon Healthcare recalled three lots of Milk of Magnesia 2400 mg/30 mL Oral Suspension, one lot of Acetaminophen 650 mg/ 20.3mL, and six lots of Magnesium Hydroxide 1200mg/Aluminum Hydroxide 1200mg/Simethicone 120 mg per 30 mL in unit dose cups to the hospital, clinic and patient level due to microbial contamination. Affected lot numbers and expiration dates can be found at the FDA website.

IDArubicin Hydrochloride Injection USP 5 mg/5 mL by Teva: Recall – Particulate Matter 3/29/22
Teva Pharmaceuticals recalled one lot of IDArubicin Hydrochloride Injection USP 5 mg/5 mL vial, (NDC 0703-4154-11; Lot 31329657B; Exp. 08/2023) to the user level in the United States based on an internal inspection that found particulate matter in one vial of the product.

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***
Artri Ajo King	Joint pain/arthritis	Diclofenac
Tawon Liar	Pain, rheumatism, insomnia, improving immune system, increasing energy, lowering cholesterol	Meloxicam
Wonderful Honey	Sexual Enhancement	Sildenafil

New Product Shortages	***Date Initially Posted***
Dextrose 10% injection	3/1/22
Streptozocin powder for injection	3/4/22
Conivaptan hydrochloride in 5% dextrose plastic container	3/14/22
Pentostatin injection	3/22/22
Technetium TC-99M mebrofenin injection	3/30/22
Semaglutide injection (Wegovy) 0.25 mg/0.5 mL and 0.5 mg/0.5 mL	3/31/22

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Accolate (Zafirlukast) Tablets (Par Pharmaceuticals): 10 mg tablets in 60-count bottles (NDC 49884-549-02), 20 mg tablets in 60-count bottles (NDC 49884-554-02); zafirlukast tablets remain available from other manufacturers.	3/17/22

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Ztalmy / Ganaxolone / Marinus Pharmaceuticals	For the treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder (CDD), a rare form of genetic epilepsy, in patients two years of age and older	3/18/22
Opdualag / Nivolumab and Relatlimab-rmbw / Bristol-Myers Squibb	For the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma	3/18/22
Pluvicto / Lutetium Lu 177 Vipivotide Tetraxetan / Advanced Accelerator Applications USA, Inc	For the treatment of adult patients with prostate-specific membrane antigen (PSMA) positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy	3/23/22
Locametz / Kit for the Preparation of Gallium Ga 68 Gozetotide Injection / Novartis	For positron emission tomography of PSMA-positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy, with suspected recurrence based on elevated PSA level, and for selection of patients with metastatic prostate cancer for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated	3/23/22

New Indications:	***Description***	***Date Approved***
Nivolumab / Opdivo / Bristol-Myers Squibb	In combination with platinum-doublet chemotherapy, for neoadjuvant treatment of adult patients with resectable non-small cell lung cancer	3/4/22
Lynparza / Olaparib / AstraZeneca	For the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy	3/11/22
Rinvoq / Upadacitinib / AbbVie	For the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers	3/16/22
Keytruda / Pembrolizumab / Merck	As a single agent for patients with advanced endometrial carcinoma that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and who are not candidates for curative surgery or radiation	3/21/22
Cabenuva / Cabotegravir and Rilpivirine / Viiv Healthcare	As a complete regimen for the treatment of HIV-1 infection in adults	3/23/22
Fintepla / Fenfluramine / Zogenix	For seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older	3/25/22

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Adlarity / Donepezil / Corium, Inc	Transdermal system; 5 mg/24 hour and 10 mg/24 hour; applied once weekly for treatment of mild, moderate, and severe dementia of the Alzheimer's type	3/11/22
Sirolimus / Hyftor / Nobelpharma America	Topical gel 0.2%; treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years and older	3/22/22
Xelstrym / Dextroamphetamine / Noven Pharmaceuticals	Transdermal system; 4.5 mg/9 hour, 9 mg/9 hour, 13.5 mg/9 hour, and 18.5 mg/9 hour; treatment of attention deficit hyperactivity disorder in adults and pediatric patients 6 years and older	3/22/22
Tilando / Testosterone Undecanoate / Antares	Capsules: 112.5 mg; testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone	3/28/22
Abacavir, dolutegravir, lamivudine / Triumeq PD / ViiV	Tablets for oral suspension; for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 10 kg	3/30/22

Compiled by:

Terri Levien, Pharm.D.
Regan Smith, Pharm.D., PGY1 Drug Information Resident
Keelin Hovrud, Doctor of Pharmacy Candidate 2022
Emily Hitt, Doctor of Pharmacy Candidate 2022

Drug Information Center
College of Pharmacy and Pharmaceutical Sciences
Washington State University
412 E. Spokane Falls Blvd.
Spokane, WA 99202-2131
(509) 358-7662
Pharmacy.druginfo@wsu.edu

Ztalmy / Ganaxolone / Marinus Pharmaceuticals	
Generic Name / Brand Name / Company	Ztalmy / Ganaxolone / Marinus Pharmaceuticals
Date of approval	3/18/22
Drug Class (Mechanism of Action if novel agent)	Positive allosteric modulator of $GABA_A$ receptors
Indication	For the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients two years of age and older
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths.	Oral suspension: 50 mg/mL.
Common Dose/sig	For patients weighing 28 kg or less: initial dose is 6 mg/kg orally three times daily; titrate to a maximum dose of 21 mg/kg three times daily based on tolerance. For patients weighing more than 28 kg: initial dose is 150 mg orally three times daily; titrate to a maximum dose of 600 mg three times daily based on tolerance.
DEA Schedule	Pending
Date of market availability	July 2022
Similar Medication Names	Brexanolone, Metaxalone
Clinical Use Evaluation	
Common Adverse Effects	≥5%: somnolence, pyrexia, respiratory tract infection, sedation, salivary hypersecretion, seasonal allergies
Severe Adverse Effects	None identified
Severe Drug-Drug Interactions	Avoid concomitant moderate and strong CYP3A4 inducers Concomitant CNS depressants can increase the risk of somnolence and sedation
Severe Drug-Food Interactions	Ganaxolone must be administered with food
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Approved for patients 2 years and older; safety and efficacy in patients younger than 2 years old have not been established.
Renal or Hepatic Dosing	There are no recommended dose adjustments for renal impairment. Patients with hepatic impairment may need a reduced dose.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	There are no labeled contraindications to ganaxolone. Warnings and precautions: Somnolence and sedation may occur. Concomitant CNS depressants may increase risk of sedation. Patients should avoid driving or using machinery until they know how ganaxolone affects them. Increased risk of suicidal behavior and ideation have been associated with antiepileptic drugs. Patients should be monitored for depression, suicidal thoughts or behavior, and unusual changes in mood or behavior. Do not abruptly stop ganaxolone due to risk of increased seizure frequency and status epilepticus associated with abrupt discontinuation of antiepileptic drugs.
Special administration technique or considerations	Ganaxolone must be administered with food. The suspension should be shaken thoroughly for at least 1 minute, and then wait for 1 minute before measuring and administering dose. Oral dosing syringe should be used to measure and administer the dose.
Prepared by	Regan Smith
Source	Ztalmy (ganaxolone) [prescribing information]. Radnor, PA: Marinus Pharmaceuticals; March 2022.

Opdualag / Nivolumab and Relatlimab-rmbw / Bristol-Myers Squibb	
Generic Name / Brand Name / Company	Nivolumab and relatlimab-rmbw/Opdualag/Bristol-Myers Squibb
Date of approval	3/18/22
Drug Class (Mechanism of Action if novel agent)	Immune checkpoint inhibitor combination: PD-1/LAG-3 blocking antibody
Indication	For the treatment of adult and pediatric patients at least 12 years of age with unresectable or metastatic melanoma
Comparative agent – Therapeutic interchange?	Nivolumab (Opdivo), ipilimumab (Yervoy), pembrolizumab (Keytruda)
Dosage forms/strengths.	Injection: nivolumab 240 mg and relatlimab 80 mg per 20 mL, single-dose vials
Common Dose/sig	Patients must weigh at least 40 kg. Dose is 480 mg nivolumab/160 mg relatlimab administered intravenously every 4 weeks.
DEA Schedule	None
Date of market availability	Available
Similar Medication Names	Opdivo
Clinical Use Evaluation	
Common Adverse Effects	≥20%: musculoskeletal pain, fatigue, rash, pruritis, diarrhea
Severe Adverse Effects	Serious adverse reactions occurred in 36% of patients: adrenal insufficiency, anemia, colitis, pneumonia, acute myocardial infarction, back pain, diarrhea, myocarditis, pneumonitis; fatal adverse reactions (0.8%): hemophagocytic lymphohistiocytosis, acute edema of the lung, pneumonitis. Severe immune-mediated adverse reactions include pneumonitis, colitis, hepatitis, endocrinopathies (hyper/hypothyroidism), hematologic adverse reactions, nephritis with renal dysfunction, myocarditis, type 1 diabetes mellitus/diabetic ketoacidosis
Severe Drug-Drug Interactions	Live vaccines should be given prior to initiation of therapy. No drug interaction studies have been performed.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Evaluate liver enzymes, creatinine, and thyroid function at baseline. Monitor the following during therapy: hemoglobin, lymphocytes, AST/ALT, sodium, creatinine.
Used in Pediatric Areas	Approved for use in those 12 years and older who weight at least 40 kg; drug exposure in this population is expected to result in safety and efficacy similar to that of the adult population.
Renal or Hepatic Dosing	No clinically important effect on clearance of either component with mild/moderate renal or hepatic impairment. Effects of severe renal/hepatic impairment on the pharmacokinetics nivolumab and relatlimab are unknown.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings Severe/fatal immune-mediated adverse reactions have been reported. Early identification and management is essential for safe use. Withhold for Grade 3 immune-mediated adverse reactions. Monitor for infusion-related reactions
Special administration technique or considerations	Can be administered diluted or undiluted. If diluting prior to administration, dilute solution with 0.9% sodium chloride injection or 5% dextrose injection. Mix gently via inversion. Do not shake. Administer infusion over 30 minutes. Flush the intravenous line at the end of the infusion. Do not co-administer other drugs through the same line.
Prepared by	Emily Hitt
Source	Opdualag (nivolumab, relatlimab) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2022.

Pluvicto / Lutetium Lu 177 Vipivotide Tetraxetan / Advanced Accelerator Applications USA, Inc	
Generic Name / Brand Name / Company	Pluvicto / Lutetium Lu 177 Vipivotide Tetraxetan / Advanced Accelerator Applications USA, Inc
Date of approval	3/23/22
Drug Class (Mechanism of Action if novel agent)	Radioligand therapeutic agent; active moiety binds to prostate-specific membrane antigen (PSMA) and induces DNA damage and cell death.
Indication	Indicated for the treatment of adult patients with PSMA-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor inhibition and taxane-based chemotherapy.
Comparative agent – Therapeutic interchange?	Radiotherapy; sipuleucel-T (Provenge)
Dosage forms/strengths.	Available as an injection in a single-dose vial.
Common Dose/sig	Recommended dosage is 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses or until disease progression or until unacceptable toxicity.
DEA Schedule	None
Date of market availability	April or May 2022
Similar Medication Names	Lutetium Lu 177 dotatate (Lutathera)
Clinical Use Evaluation	
Common Adverse Effects	Most common adverse reactions (≥20%): fatigue, dry mouth, nausea, anemia, decreased appetite, constipation; common laboratory abnormalities (≥30%): decreased lymphocytes, decreased hemoglobin, decreased leukocytes, decreased platelets, decreased calcium, and decreased sodium.
Severe Adverse Effects	Serious adverse reactions occurred in 36% of patients: hemorrhage, musculoskeletal pain, sepsis, anemia, urinary tract infection, acute kidney injury, pneumonia, pancytopenia, spinal cord compression, pulmonary embolism. Fatal adverse reactions occurred in 2.8% of patients: sepsis, pancytopenia, hepatic failure, intracranial hemorrhage, subdural hematoma, ischemic stroke, COVID-19 and aspiration pneumonia.
Severe Drug-Drug Interactions	Not a substrate of transporters or CYP450 enzymes.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Complete blood count (CBC) and kidney function (SCr and calculated CrCl) before and during treatment
Used in Pediatric Areas	Safety and effectiveness in pediatric patients have not been established.
Renal or Hepatic Dosing	Patients with mild/moderate renal impairment may be at a higher risk for renal toxicity. Pharmacokinetics and safety have not been studied in patients with severe renal impairment or end-stage renal disease.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none. Warnings: myelosuppression, renal toxicity, embryo-fetal toxicity, infertility Use waterproof gloves and effective radiation shielding to minimize radiation exposure when handling. Patients should remain well hydrated and urinate frequently before/after administration of the drug. Precautions should be followed to minimize radiation exposure after the patient is released. Patients should: • Limit close contact with household contacts for 2 days or children/pregnant women for 7 days. • Refrain from sexual activity for 7 days. • Sleep in a separate bedroom from household contacts for 3 days, children for 7 days or pregnant women for 15 days. • Use contraception during treatment and for 14 weeks after the last dose.

Special administration technique or considerations	Should only be used by healthcare providers who are qualified with training and experience in handling radiopharmaceuticals. Use aseptic technique and radiation shielding when handling/administering this drug. May be administered intravenously as an injection using a disposable syringe with a syringe shield, as an infusion using the gravity method or as an infusion using the vial. • Reduce the dose with the syringe or vial method. • Prior to administration, flush the intravenous catheter with ≥10 mL of 0.9% sterile sodium chloride solution.
Prepared by	Emily Hitt
Source	Pluvicto (lutetium Lu 177 vipivotide tetraxetan) [prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; March 2022.