WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 7/1/25 – 7/31/25

FDA Drug Safety Communications & Drug Information Updates:

Endothelin Receptor Antagonists: REMS for Embryofetal Toxicity Risk Removed 7/8/25
The FDA has determined that REMS requirements for embryofetal toxicity risks are no longer necessary to ensure the benefits of the endothelin receptor antagonists outweigh the risks. The current labeling was determined to sufficiently communicate the risk and will continue to be used to inform health care professionals and patients of the risks. The eliminated REMS were for ambrisentan (Letairis and generics), macitentan (Opsumit and generics, Opsynvi), aprocitentan (Tryvio). The REMS for bosentan (Tracleer and generics) and sparsentan (Filspari) were modified to remove the requirements related to embryofetal toxicity risks, but REMS requirements related to hepatotoxicity remain in effect.

Elevidys (delandistrogene moxeparvovec): Deaths Due to Acute Liver Failure 7/18/25
Following FDA announcement in June that they were investigating deaths associated with liver toxicity in patients with Duchenne muscular dystrophy treated with Elevidys gene therapy, and an FDA update in July, Sarepta agreed to add a black box warning for acute liver injury and acute liver failure. Sarepta also paused shipment of Elevidys for non-ambulant patients, while shipment of product for ambulant patients has resumed.

FDA Recommends Scheduling 7-OH: MedWatch Communication 7/29/25
The FDA announced steps being taken to recommend scheduling 7-hydroxymitragynine (7-OH), a concentrated byproduct of the Kratom plant that binds opioid receptors and has the potential for abuse.

Labeling Changes for Opioid Pain Medications: Drug Safety Communication 7/31/25
The FDA is requiring labeling changes to all opioid pain medications emphasizing and explaining risks associated with their long-term use. Manufacturers have 30 days to submit updated labeling which must include summary risk information, dosing warnings, use limits, treatment guidance, reminder not to abruptly discontinue opioids, information on overdose reversal agents, enhanced drug interaction warning, information about toxic leukoencephalopathy, and information about opioid-related esophageal problems.

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

Sigma Spectrum Infusion System, Baxter: Early Alert 7/1/25
The FDA reported that Baxter has issued a letter to affected customers advising that certain Sigma Spectrum Infusion Systems (V6 and V8 platforms) be removed from use. In some units the incorrect software was installed (V8 software on a V6 pump or V6 software on a V8 pump) which may result in inaccurate flow rates. Software versions on affected pumps require servicing by contacting Baxter. A complete list of affected serial numbers can be found on the FDA site.

Sucralfate, Nostrum Laboratories Inc: Recall – Discontinuation 7/14/25
Nostrum Laboratories Inc recalled all lots of sucralfate 1 g within expiry, manufactured by Nostrum Labs after June 2023. The company has shut down operations resulting in termination of all quality activities necessary to guarantee all product will meet all intended specifications through the labeled shelf life.

Alaris and BD Alaris Pump Modules; BD Alaris Pump Module model 8100: Global Recall 7/8/25, 7/15/25
Alaris and BD Alaris have issued a Global Recall, updating their July 8 Early Recall letter regarding the BD Alaris Pump Module model 8100, to include all their pump modules that have been or may have been serviced with Legacy Bezel Kit assemblies. These Legacy Bezel Kit assemblies have been identified to contain components like the model 8100-associated pump module. Corrective actions on the part of the user are suggested in a letter to customers and can be found on the FDA site. Some pumps may continue to be used. The pump modules with these defective components have been associated with serious injuries and death.

On July 8, BD and CareFusion had issued an Early Recall (correction) stating that their Pump Module model 8100 was manufactured with potentially high-risk defective parts. The deviations in performance were observed in relation to the use of filters and other in-line components and may impact flow rate accuracy and time to alarm. Additional information on this recall letter can be found here. Company recommendations for this model's pump modules are included in the global recall as stated above.

Cefazolin for Injection USP 1 g, Sandoz Inc.: Recall Expansion – Additional Lot Recalled 7/15/25
One additional lot number of Cefazolin for Injection, USP, 1 gram per vial was recalled by Sandoz Inc. due to a customer complaint of 4 vials being mislabeled as Penicillin G for Injection included in Cefazolin for Injection cartons. The affected lots, including the expanded lot number, are listed on the FDA site.

Dexcom Continuous Glucose Monitor Receivers, Dexcom Inc: Recall – Speaker Malfunction 7/17/25
Dexcom Inc recalled certain Dexcom G6, Dexcom G7, Dexcom ONE, and Dexcom ONE+ receivers due to speaker malfunction that may cause it to fail to make an alert sound when blood glucose is dangerously high or low. A full list of Unique Device Identifier (UDI)/Model numbers and lot/serial numbers can be found on the FDA site.

Microbore Extension Set, B. Braun Medical: Early Alert – Incorrectly Labeled 7/17/25
B. Braun Medical recalled select lot number of the Microbore Extension Set model number V6215 due to incorrect labeling. The affected units incorrectly show that the device contains an air eliminating filter when it does not and is not indicated for the removal of air. Affects units should be removed from use. A complete lis of affected lots can be found on the FDA site.

Novum IQ Large Volume Pumps, Baxter: Early Alert 7/22/25
Baxter has issued a letter to affected customers saying that their Novum IQ Large Volume Pumps (LVP) have been reported to under- or over-infuse medication. This issue is potentially due to misloading of the tubing into the pump channel and may occur when changing flow rate or giving bolus doses. Baxter recommends all Novum IQ LVP devices to be corrected prior to continuation of use. All serial numbers are reported to be affected; product code is 40700BAXUS (UDI-DI 05413765851797). The FDA site has corrective actions given by Baxter for these devices.

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***
Black Horse Miracle Honey for Men	Sexual enhancement	Sildenafil, tadalafil
Black Panther Miracle Honey for Men	Sexual enhancement	Sildenafil, tadalafil, acetaminophen
FATZorb	Weight loss	Sibutramine[1], desmethyl sibutramine, benzyl sibutramine, phenolphthalein[2]
Secret Miracle Honey Extra Strength	Sexual enhancement	Sildenafil, tadalafil, acetaminophen
Versace Real Honey for Men	Sexual enhancement	Sildenafil, tadalafil, acetaminophen

*recalled

[1]Sibutramine has been associated with increased cardiovascular events; removed from market for safety reasons in 2010[FDA]

[2]Phenolphthalein was an over-the-counter laxative that is no longer marketed in the US due to carcinogenicity concerns

New Product Shortages (per FDA or ASHP)	***Date Initially Posted***
Bacteriostatic water for injection	7/15/25
Dextroamphetamine extended-release capsules	7/16/25
Mometasone furoate aerosol for oral inhalation	7/29/25

ASHP Drug Shortages List contains up to-date information on drug shortages

Brand Name or Only Source Product Discontinuations/Withdrawals	***Date Posted***
Oseltamivir capsule 30 mg (Tamiflu, Genentech): generics remain available	7/8/25
Levothyroxine tablets, all strengths (Euthyrox, EMD Serono): therapeutic equivalent generics remain available	7/10/25
Ethionamide tablet 250 mg (Trecator, Pfizer): manufacturing discontinued and supply expected to be exhausted in September 2025; alternative antimicrobials are available for use in tuberculosis treatment	7/16/25
Oxaprozin tablet 600 mg (Daypro, Hospira); generics remain available	7/17/25
Potassium chloride tablet, extended release 600 mg (8 mEq) and 750 mg (10 mEq) (Klor-Con, Upsher-Smith Laboratories); generics remain available	7/23/25
Glipizide tablet, extended-release 10 mg (Glucatrol XL, Pfizer): manufacturing now discontinued for all strengths, generics remain available	7/24/25
Voriconazole tablets 50 mg (Vfend, Pfizer); generics and alternative formulations remain available	7/28/25
Esterified estrogens (Menest, Pfizer); no other esterified estrogens product is available	7/29/25

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Linvoseltamab-gcpt/Lynozyfic/Regeneron	Bispecific antibody for the treatment of patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody	7/2/25
Sunvozertinib/Zegfrovy/Dizal	Kinase inhibitor for treatment of patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy	7/2/25
Sebetralstat/Ekterly/KalVista Pharmaceuticals	Plasma kallikrein inhibitor for the treatment of acute attacks of hereditary angioedema in adult and pediatric patients 12 years and older	7/7/25
Delgocitinib/Anzupgo/Leo Pharma	Topical pan-Janus kinase inhibitor for the treatment of moderate-to-severe chronic hand eczema in adults for whom topical corticosteroids are inadequate or not advisable	7/23/25
Sepiapterin/Sephience/PTC Therapeutics	Phenylalanine hydroxylase activator for the treatment of hyperphenylalaninemia in patients 1 month of age and older with siapterin-responsive phenylketonuria	7/28/25
Aceclidine/Vizz/LENZ Therapeutics Inc	Cholinergic agonist ophthalmic solution for the treatment of presbyopia (far sightedness) in adults	7/31/25

New Indications:	***Description***	***Date Approved***
Finerenone/Kerendia/Bayer	Treatment of patients with heart failure with left ventricular ejection fraction ≤40%	7/14/25
COVID-19 Vaccine/Spikevax/Moderna	Vaccination in children 6 months through 11 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19; previously available through EUA for all children in this age group	7/10/25
Apremilast/Otezla/Amgen Inc.	Adults and children 6 years of age and older with active psoriatic arthritis	7/23/25
Avatrompbopag/Doptelet/AkaRx Inc	Indication for tablet formulation expanded to include pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia who have had an insufficient response to a previous treatment	7/24/25
Bedaquiline/Sirturo/Janssen Therapeutics	Indication for treatment of pulmonary tuberculosis due to Mycobacterium tuberculosis resistant to at least rifampin and isoniazid as part of a combination regimen expanded to include patients 2 years to 5 years weighing at least 8 kg	7/28/25
Lonapegsomatropin-tcgd/Skytrofa/ Ascendis Pharma	For the replacement of endogenous growth hormone in adults with growth hormone deficiency	7/28/25
Pegcetacoplan/Empaveli/Apellis Pharmaceuticals	Treatment of adult and pediatric patients 12 years and older with C3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis to reduce proteinuria	7/28/25
Concizumab-mtci/Alhemo/Novo Nordisk	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years and older with hemophilia A without FVIII inhibitors and hemophilia B without FIX inhibitors	7/31/25
Inclisiran/Leqvio/Novartis Pharmaceuticals	As monotherapy alongside diet and exercise to lower LDL cholesterol in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia	7/31/25

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Vancomycin/Tyzavan/Hikma	Injection: 500 mg/100 mL, 750 mg/150 mL, 1 g/200 mL, 1.25 g/250 mL, 1.5 g/300 mL, 1.75 g/350 mL, 2 g/400 mL; ready to infuse formulation supplied in single-dose bag that can be stored at room temperature	7/2/25
Ramipril/Vostally/Metacel Pharmaceuticals LLC	Oral solution: 1 mg/mL in 150 mL bottle; treatment of hypertension in adults, in patients 55 years or older to reduce risk of major cardiovascular events, and in adults with post-myocardial infarction heart failure	7/23/25
Amlodipine/Sdamlo/Brillian Pharma	Powder for oral solution: 2.5 mg, 5 mg, 10 mg; treatment of hypertension in patients 6 years and older and treatment of coronary artery disease in adults	7/24/25
Avatrombopag/Doptelet Sprinkle/AkaRx Inc	Capsules containing oral granules: 10 mg; treatment of thrombocytopenia in pediatric patients 1 year to less than 6 years with persistent or chronic immune thrombocytopenia	7/24/25
Celecoxib/Vyscoxa/Carwin Pharmaceutical Associates	Oral suspension: 10 mg/mL supplied in 473 mL bottle; indicated in adults for osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and for patients 2 years and older for juvenile rheumatoid arthritis. Take on an empty stomach.	7/29/25
Methocarbamol/Atmeksi/Metacel Pharmaceuticals	Oral suspension: 750 mg/5 mL supplied in 150 mL bottle; muscle relaxant for use in patients 16 years and older	7/30/25

Compiled by:
Terri Levien, Pharm.D.
Hayden Wesley, Pharm.D.
Alexander Hatkoff, Doctor of Pharmacy Candidate 2025

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

Linvoseltamab-gcpt/Lynozyfic/Regeneron	
Generic Name / Brand Name / Company	Linvoseltamab-gcpt/Lynozyfic/Regeneron
Date of approval	7/2/25
Drug Class (Mechanism of Action if novel agent)	Bispecific antibody
Indication	Treatment of patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 5 mg/2.5 mL or 200 mg/10 mL solution in a single-dose vial
Common Dose/sig	Step-up doses of 5 mg, 25 mg, and 200 mg weekly, followed by 200 mg weekly for 10 doses, then 200 mg every 2 weeks.
DEA Schedule	N/A
Date of market availability	Available only through REMS
Similar Medication Names	Lynparza
Clinical Use Evaluation	
Common Adverse Effects	Musculoskeletal pain, cough, cytokine release syndrome (CRS) upper respiratory tract infection, diarrhea, fatigue, pneumonia, nausea, headache, dyspnea (≥ 20%)
Severe Adverse Effects	CRS, neurologic toxicity (ICANS), infections, neutropenia, hepatotoxicity
Severe Drug-Drug Interactions	May suppress CYP450 activity
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	CBC at baseline and follow up, liver enzymes and bilirubin at baseline, immunoglobulin levels
Used in Pediatric Areas	Not established
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: CRS and neurologic toxicity (boxed warning and REMS), infections, neutropenia, hepatotoxicity, embryo-fetal toxicity Patients should be hospitalized for 24 hours after first and second step-up doses (days 1 and 8).
Special administration technique or considerations	Administer pretreatment medications (acetaminophen, diphenhydramine, dexamethasone) through at least the second treatment dose. Use of a 0.2- to 5-micron polyethersulfone filter required. Flush IV line with 0.9% NaCl. Total infusion time should include line flush. Store diluted drug at room temperature for 8 hours or refrigerated for 48 hours.
Prepared by	Alexander Hatkoff
Source	Lynozyfic (linvoseltamab-gcpt) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; July 2025.

Sunvozertinib/Zegfrovy/Dizal	
Generic Name / Brand Name / Company	Sunvozertinib/Zegfrovy/Dizal
Date of approval	7/2/25
Drug Class (Mechanism of Action if novel agent)	Kinase inhibitor
Indication	Treatment of patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy
Comparative agent – Therapeutic interchange?	Amivantamab
Dosage forms/strengths	Tablets: 150 mg and 200 mg
Common Dose/sig	200 mg orally once daily taken with food
DEA Schedule	N/A
Date of market availability	Currently unknown
Similar Medication Names	Wegovy
Clinical Use Evaluation	
Common Adverse Effects	Diarrhea, rash, decreased appetite, stomatitis, fatigue, nausea, paronychia, vomiting, constipation, musculoskeletal pain, pruritus, dry skin, urinary tract infection, abdominal pain, decreased weight (≥ 20%)
Severe Adverse Effects	Pneumonia, dyspnea, pancreatitis, device related infection and rash, thrombosis, COVID-19 infection, interstitial lung disease
Severe Drug-Drug Interactions	Avoid use with CYP3A inhibitors or reduce dose to 150 mg. Avoid use with CYP3A inducers or increase dose to 400 mg. With P-gp and BRCP substrates, monitor for adverse reactions. Avoid concomitant hormonal contraceptives.
Severe Drug-Food Interactions	None observed
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Chemistry and hematology as clinically indicated
Used in Pediatric Areas	Not established
Renal or Hepatic Dosing	None; severe hepatic and renal impairment not studied
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none Warnings: interstitial lung disease, pneumonitis, diarrhea, nausea, vomiting, rash, ocular toxicity, embryo-fetal toxicity
Special administration technique or considerations	Take with food to reduce GI side effects.
Prepared by	Alexander Hatkoff
Source	Zegfrovy (sunvozertinib) [prescribing information]. Shanghai, China: Dizal Pharmaceutical Co., Ltd.; July 2025.

Sebetralstat/Ekterly/KalVista Pharmaceuticals	
Generic Name / Brand Name / Company	Sebetralstat/Ekterly/KalVista Pharmaceuticals
Date of approval	7/7/25
Drug Class (Mechanism of Action if novel agent)	Plasma kallikrein inhibitor
Indication	Treatment of acute attacks of hereditary angioedema in adult and pediatric patients 12 years and older
Comparative agent – Therapeutic interchange?	Similar agents: ecallantide, berotralstat
Dosage forms/strengths	Tablets: 300 mg
Common Dose/sig	Two, 300 mg tablets taken orally when HAE attack occurs. Second dose of 600 mg may be taken 3 hours after the first if symptoms worsen (max 1,200 mg).
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Berotralstat
Clinical Use Evaluation	
Common Adverse Effects	Headache (≥ 2%)
Severe Adverse Effects	None
Severe Drug-Drug Interactions	Avoid use with strong CYP3A4 inhibitors. Reduce dose to one 300 mg tablet when taken with weak-moderate CYP3A4 inhibitors. Use with strong and moderate CYP3A4 inducers not recommended. No modification necessary for weak CYP3A4 inducers.
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	Indicated for patients 12 years and older. Safety and effectiveness in patients younger than 12 years not established.
Renal or Hepatic Dosing	Renal adjustment: none Hepatic adjustment: mild impairment (Child-Pugh Class A), no change. Moderate impairment (Child-Pugh Class B), reduce dose to one 300 mg tablet. Avoid use in severe impairment (Child-Pugh Class C).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications/warnings: none
Special administration technique or considerations	Take at earliest sign of HAE. Administer second dose as needed at least 3 hours after the first.
Prepared by	Alexander Hatkoff
Source	Ekterly (sebetralstat) [prescribing information]. Cambridge, MA: KalVista Pharmaceuticals Inc.; July 2025.

Delgocitinib/Anzupgo/Leo Pharma	
Generic Name / Brand Name / Company	Delgocitinib/Anzupgo/Leo Pharma
Date of approval	7/23/25
Drug Class (Mechanism of Action if novel agent)	Pan-Janus kinase inhibitor; inhibits the JAK-STAT pathway blocking activity of JAK1, JAK2, JAK3, and tyrosine kinase 2 to suppress inflammatory response
Indication	Treatment of moderate-to-severe chronic hand eczema in adults for whom topical corticosteroids are inadequate or not advisable
Comparative agent – Therapeutic interchange?	None; short-term oral corticosteroids
Dosage forms/strengths	Cream: 20 mg/g; supplied in 30 g and 60 g tubes
Common Dose/sig	Apply twice daily to skin of affected areas only on hands and wrists
DEA Schedule	N/A
Date of market availability	Late September or early October 2025
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	(≤1%): application site pain, paresthesia, pruritus, erythema, bacterial skin infections including finger cellulitis, paronychia, other skin infections, leukopenia, neutropenia
Severe Adverse Effects	Eczema herpeticum, herpes zoster
Severe Drug-Drug Interactions	Other JAK inhibitors or potent immunosuppressants: concomitant use not recommended Live vaccines: avoid use immediately prior to, during, or immediately after delgocitinib treatment
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 have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: serious infections, non-melanoma skin cancers; unknown if it is associated with risks related to JAK inhibition
Special administration technique or considerations	Complete any necessary vaccinations prior to treatment. Apply in a thin layer. Do not use more than 30 g per 2 weeks or 60 g per month. If applying on someone else, wash hands after applying.
Prepared by	Terri Levien
Source	Anzupgo (delgocitinib) [prescribing information]. Madison, NJ: LEO Pharma Inc; July 2025.

Sepiapterin/Sephience/PTC Therapeutics	
Generic Name / Brand Name / Company	Sepiapterin/Sephience/PTC Therapeutics
Date of approval	7/28/25
Drug Class (Mechanism of Action if novel agent)	Phenylalanine hydroxylase activator
Indication	For use in conjunction with a phenylalanine-restricted diet in the treatment of hyperphenylalaninemia in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria
Comparative agent – Therapeutic interchange?	Sapropterin
Dosage forms/strengths	Oral powder: 250 mg, 1000 mg
Common Dose/sig	Administered once daily with food; recommended starting dose: 7.5 mg/kg if less than 6 months of age, 15 mg/kg if 6 months to less than 1 year, 30 mg/kg if 1 year to less than 2 years, and 60 mg/kg if 2 years and older
DEA Schedule	N/A
Date of market availability	Mid-August 2025
Similar Medication Names	Sapropterin
Clinical Use Evaluation	
Common Adverse Effects	≥2%: diarrhea, headache, abdominal pain, hypophenylalaninemia, feces discoloration, oropharyngeal pain
Severe Adverse Effects	Bleeding
Severe Drug-Drug Interactions	Levodopa: monitor for change in neurologic status Dihydrofolate reductase inhibitors: avoid concomitant use Sepiapterin reductase inhibitors: avoid concomitant use Drugs affecting nitric oxide mediated vasorelaxation (eg, PDE5 inhibitors): monitor blood pressure
Severe Drug-Food Interactions	None known; administer with food
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Obtain baseline phenylalanine before initiating. Check blood phenylalanine levels within 2 weeks to determine response and need for dose titration. Discontinue if blood phenylalanine does not decrease after 2 weeks of treatment at maximum dose of 60 mg/kg
Used in Pediatric Areas	Indicated in patients 1 month of age and older
Renal or Hepatic Dosing	No dosage adjustment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: may increase bleeding risk Hypophenylalaninemia may occur, monitor blood phenylalanine levels
Special administration technique or considerations	Must be taken with food. Empty contents of prescribed number of packets into a container for mixing, slowly add water, apple juice, strawberry jam, or applesauce to the powder and stir for 30 seconds or more until free of lumps (60 seconds or more for jam or applesauce). If any mixture remains in container after administration, rinse with water or apple juice and swallow right away, repeating until no mixture remains in container. For doses less than 1 g, mix with water or apple juice and administer with an oral dosing syringe.
Prepared by	Terri Levien
Source	Sephience (sepiapterin) [prescribing information]. Warren, NJ: PTC Therapeutics, Inc; July 2025.

Aceclidine/Vizz/LENZ Therapeutics Inc	
Generic Name / Brand Name / Company	Aceclidine/Vizz/LENZ Therapeutics Inc
Date of approval	7/31/25
Drug Class (Mechanism of Action if novel agent)	Cholinergic agonist; pupil selective miotic
Indication	Treatment of presbyopia (far sightedness) in adults
Comparative agent – Therapeutic interchange?	Pilocarpine 0.4% (Qlosi), pilocarpine 1.25% (Vuity)
Dosage forms/strengths	Ophthalmic solution: 1.44% in 0.4 mL single-dose vial; packaged in foil pouch containing 5 single-dose vials
Common Dose/sig	Instill one drop in each eye, wait 2 minutes and instill a second drop in each eye once daily
DEA Schedule	N/A
Date of market availability	October 2025
Similar Medication Names	Acetylcysteine
Clinical Use Evaluation	
Common Adverse Effects	Instillation site irritation (20%), dim vision (16%), headache (13%)
Severe Adverse Effects	Retinal tears or detachment have been reported with miotics
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	Not indicated for use in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments or precautions
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: blurred vision, temporary dim or dark vision, caution driving Retinal tear or detachment risk Use with caution if history of iritis Not recommended if hypersensitivity to any product ingredient
Special administration technique or considerations	Remove contact lenses before instillation; may reinsert lenses 10 minutes after instillation. If more than one topical ophthalmic product is being used, separate administration by at least 5 minutes. Avoid touching single-dose vial to the eye or any other surface.
Prepared by	Terri Levien
Source	Vizz (aceclidine) [prescribing information]. Solana Beach, CA: LENZ Therapeutics, Inc; July 2025.