WASHINGTON STATE UNIVERSITY
College of Pharmacy and Pharmaceutical Sciences

Drug Information Center

Highlights of FDA Activities – 12/1/25 – 12/31/25

FDA Drug Safety Communications & Drug Information Updates:

Andexxa (coagulation factor Xa [recombinant], inactivated-zhzo) – FDA Safety Communication 12/18/25
Following review of postmarketing safety data on thromboembolic events in patients treated with Andexxa, the FDA has determined that the serious risks including thromboembolic events outweigh its benefits. AstraZeneca has submitted a request to voluntarily withdraw the product from the market, ending US sales by December 22, 2025.

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

FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors: Early Alert – Incorrect Low Glucose Readings 12/2/25
Abbott Diabetes Care issued an alert to distributors, health care providers, and patients recommending certain glucose monitor sensors be removed from use as they have provided incorrect low glucose readings which may result in wrong treatment decisions such as excessive carbohydrate intake or skipping insulin doses. A list of affected lots and serial numbers can be found on the FDA site, along with instructions for locating the sensor serial number.

ByHeart Whole Nutrition Infant Formula: Recall – Infant Botulism 12/3 & 12/10/25
The FDA updated information on the ongoing recall and investigation of ByHeart Whole Nutrition Infant Formula and an outbreak of infant botulism. All ByHeart Whole Nutrition Infant Formula products have been recalled, including all formula cans and single-serve "anywhere pack" sticks, and should not be sold or used. The FDA continues to investigate the multistate outbreak of infant botulism, with epidemiologic and laboratory data showing the recalled formula might be contaminated with *Clostridium botulinum*; six samples have tested positive. As of 12/10/25, a total of 51 infants with suspected or confirmed infant botulism and confirmed exposure to ByHeart Whole Nutrition infant formula from various lots have been reported from 19 states.

ReBoost Nasal Spray: Recall – Polymicrobial Contamination 12/10/25
MediNatura New Mexico, Inc issued a recall of their ReBoost brand intranasal spray, stating yeast and bacteria have been found within one lot of this product, lot #224268 with expiration of 12/2027 (NDC 62795-4005-9 and UPC 787647). Products have been sold across the country; however, local consumers can contact recall@MediNatura.com for refunds. All products should be discontinued as the FDA states there is reasonable probability of serious harm, and all consumers should contact their healthcare providers if they experience abnormal effects from taking this product including signs of new or worsened congestion or nasal discharge.

Dexcom G6 Continuous Glucose Monitoring System app: Correction – Unexpected App Termination 12/29/25
Dexcom, Inc has issued a correction for the Dexcom G6 Continuous Glucose Monitoring System's G6 and G6 Pro Android US CGM App version 1.15.0 due to a bug that can cause the app to terminate unexpectedly and without notification resulting in users not receiving estimated glucose values, alarms, or alerts.

IV Gravity Burette Set, ICU Medical: Recall – Missing Shut-off Valve 12/30/25
ICU Medical recalled the IV Gravity Burette Set due to a missing internal shut-off valve in the burette component that is intended to stop fluid flow. The affected products are item numbers B33359 (lot #s 14070544 and 14126963) and B9213 (lot 14130197).

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***
ClearLife Nasal Spray, MediNatura New Mexico*	Homeopathic nasal spray	Yeast/mold and microbial contamination
GE Labs Ykarine	Bodybuilding	Trendione[1]
Gold Star Distribution, Inc FDA-regulated food, drug, and dietary supplement products*	Various	Salmonella contamination, presence of rodent and avian contamination, and insanitary conditions
MR.7 SUPER 700000, StuffbyNainax LLC*	Male enhancement	Sildenafil, tadalafil
ReBoost Nasal Spray, MediNatura New Mexico*	Homeopathic nasal spray	Yeast/mold and microbial contamination
Rheumacare Ayurvedic Proprietary Medicine	Ayurvedic drug	Lead, mercury, strychnine, brucine toxins, arsenic
Rheumacare Capsules by Virgo, Navafresh*	Joint pain	Lead

*recalled

[1]Trendione (estra-4,9,11-triene-3,17-dione) is an anabolic steroid classified as a schedule III controlled substance

New Product Shortages (per FDA or ASHP)	***Date Initially Posted***
Arginine hydrochloride injection	12/2/25
Dasiglucagon	12/2/25
Isocarboxazid	12/5/25
Acyclovir sodium injection	12/16/25
Meperidine oral solution	12/22/25

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

Brand Name or Sole Source Product Discontinuations/Withdrawals	***Date Posted***
Phenoxybenzamine capsule (Dibenzyline, Advanz Pharma); generic not available - alternatives in pheochromocytoma include selective alpha-blockers such as doxazosin, terazosin, or prazosin	12/1/25
Nilutamide tablet (Nilandron, Advanz Pharma); generics remain available	12/1/25
Posaconazole injection (Noxafil, Merck Sharp & Dohme); generics remain available	12/2/25
Spironolactone tablet (Aldactone, Pfizer); generics remain available	12/10/25
Doxercalciferol injection (Hectorol, Sanofi-Aventis); generics remain available	12/10/25
Coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa, AstraZeneca); primary alternative is 4-factor prothrombin complex concentrates	12/18/25
Carbamazepine capsule, extended release (Carbatrol, Takeda); generics remain available	12/19/25

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Etuvetidigene autotemcel/Waskyra/ Fondazione Telethon ETS	Autologous hematopoietic stem cell-based gene therapy for the treatment of adults and pediatric patients 6 months and older with Wiskott-Aldrich syndrome with mutation in the WAS gene and for whom hematopoietic stem cell transplantation is appropriate and no suitable human leukocyte antigen-matched related donor is available	12/9/25
Etripamil/Cardamyst/Milestone Pharmaceuticals USA	Calcium channel blocker for conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia to sinus rhythm in adults	12/12/25

New Drug Approvals continued	***Description (See Attached Drug Summaries)***	***Date Approved***
Lerodalcibep-liga/Lerochol/LIB Therapeutics	PCSK9 inhibitor to reduce LDL cholesterol when used alongside changes in diet and exercise among adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia	12/12/25
Zoliflodacin/Nuzolvence/La Jolla Pharmaceutical	Antibacterial for treatment of uncomplicated urogenital gonorrhea in adults and children 12 years and older who weigh at least 35 kg (77 pounds)	12/12/25
Depemokimab-ulaa/Exdensur/ GlaxoSmithKline	Interleukin-5 blocking monoclonal antibody as an add-on treatment for patients 12 years and older with severe asthma	12/16/25
Aficamten/Myqorzo/Cytokinetics Incorpo	Cardiac myosin inhibitor for treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy to improve functional capacity and symptoms	12/19/25
Narsoplimab-wuug/Yartemlea/ Omeros	MASP-2 inhibitor for treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy in patients 2 years and older	12/23/25
Tradipitant/Nereus/Vanda Pharmaceuticals	Neurokinin-1 receptor antagonist for the prevention of motion sickness in adults	12/30/25

New Indications:	***Description***	***Date Approved***
Pirtobrutinib/Jaypirca/Eli Lilly and Co.	Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic leukemia previously treated with a covalent Bruton tyrosine kinase inhibitor	12/3/25
Lisocabtagene maraleucel/Breyanzi/ Bristol Myers Squibb	Treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least two prior lines of systemic therapy	12/4/25
Omidubicel-onlv/Omisirge/Gamida Cell Ltd	Treatment of adult and pediatric patients 6 years and older with severe aplastic anemia following reduced intensity conditioning and for whom a compatible donor is not available	12/8/25
Gepotidacin/Blujepa/GlaxoSmithKline	Treatment of uncomplicated urogenital gonorrhea in adult and pediatric patients 12 years and older weighing at least 45 kg who have limited or no alternative treatment options	12/11/25
Inebilizumab-cdon/Uplinza/Amgen	Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor or anti-muscle specific tyrosine kinase antibody positive	12/11/25
Niraparib and abiraterone acetate/ Akeega/Johnson & Johnson	In combination with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA2-mutated metastatic castration-sensitive prostate cancer	12/12/25
Flibanserin/Addyi/Sprout Pharmaceuticals	Indication expanded to include postmenopausal women less than 65 years of age who report emotional stress due to low sex drive	12/13/25
Fam-trastuzumab deruxtecan-nxki/Enhertu/AstraZeneca	In combination with pertuzumab for the first-line treatment of adult patients with unresectable or metastatic HER2-positive breast cancer	12/15/25
Cariprazine/Vraylar/AbbVie	Indication expanded to include treatment of schizophrenia in pediatric patients 13 to 17 years old and treatment of manic or mixed episodes associated with bipolar I disorder in pediatric patients 10 to 17 years old	12/18/25

New Indications continued:	***Description***	***Date Approved***
Nerandomilast/Jascayd/Boehringer Ingelheim	Treatment of progressive pulmonary fibrosis (PPF) in adults	12/19/25
Tirzepatide/Mounjaro/Eli Lilly & Co.	Indication expanded to include treatment of type 2 diabetes mellitus in pediatric patients 10 to 16 years of age	12/19/25
Ferric maltol/Accrufer/	Indication expanded to include treatment of iron deficiency in patients ages 10 years and older	12/22/25
Caplacizumab-yhdp/Cablivi/Genzyme	Indication expanded to include adolescents aged 12 years and older with acquired thrombotic thrombocytopenic purpura	12/23/25
Furosemide/Furoscix/ scPharmaceuticals	Indication expanded to include treatment of edema in pediatric patients weighing 43 kg and greater with chronic heart failure or chronic kidney disease, including nephrotic syndrome	12/23/25

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Berotralstat/Orladeyo/BioCryst Pharmaceuticals	Oral pellets: 72 mg, 96 mg, 108 mg, 132 mg; for prophylaxis to prevent attacks of hereditary angioedema in pediatric patients 2 years to less than 12 years	12/11/25
Trofinetide/Daybue Stix/Acadia Pharmaceuticals	Oral solution: 5,000 mg; 6,000 mg; 8,000 mg; 10,000 mg; 12,000 mg; for the treatment of Rett syndrome in adults and pediatric patients 2 years and older	12/11/25
Sildenafil/Vybrique/IBSA Pharma	Oral film: 25 mg, 50 mg, 75 mg, 100 mg; for the treatment of erectile dysfunction	12/16/25
Amivantamab and hyaluronidase-lpuj/Rybrevant Faspro/Janssen Biotech	Subcutaneous injection: amivantamab 1600 mg and hyaluronidase 20,000 units per 10 mL or amivantamab 2240 mg and hyaluronidase 28,000 units in single dose vials; for the treatment of nonsmall cell lung cancer in a combination regimen or as a single agent	12/17/25
Mosunetuzumab/Lunsumio Velo/ Genentech	Subcutaneous injection: 5 mg, 45 mg; for the treatment of adult patients with relapsed or refractory follicular lymphoma following 2 or more lines of systemic therapy	12/19/25
Semaglutide/Wegovy/Novo Nordisk	Tablets: 1.5 mg, 4 mg, 9 mg, 25 mg; for use in combination with a reduced calorie diet and increased physical activity to reduce risk of major adverse cardiovascular events in adults with established CV disease and either obesity or overweight, or to reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition	12/22/25
Mitapivat/Aqvesme/Agios Pharmaceuticals	Tablets: 100 mg; treatment of anemia in adults with alpha- or beta-thalassemia	12/24/25

Compiled by:

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Etuvetidigene autotemcel/Waskyra/ Fondazione Telethon ETS	
Generic Name/Brand Name/Company	Etuvetidigene autotemcel/Waskyra/ Fondazione Telethon ETS
Date of approval	12/9/25
Drug Class (Mechanism of Action if novel agent)	Autologous hematopoietic stem cell-based gene therapy
Indication	Treatment of adults and pediatric patients 6 months and older with Wiskott-Aldrich syndrome with a mutation in the WAS gene and for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen-matched related stem cell donor is available
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	One to eight infusion bags containing suspension of 2-11.4 x 10^6 cells/mL (1.9-11.4 x 10^6 CD34+ cells/mL) in a cryopreservative solution
Common Dose/sig	Dosing is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight at the time of infusion. The minimum recommended dose is 7 x 10^6 CD34+ cells/kg.
DEA Schedule	N/A
Date of market availability	December 2025
Similar Medication Names	Vasculera
Clinical Use Evaluation	
Common Adverse Effects	>20%: catheter related infections, bacterial and viral infections, diarrhea, vomiting, stomatitis, liver injury, head injury, rhinitis, cough, rash, petechiae, hypersensitivity, anemia, febrile neutropenia, epistaxis, pyrexia, catheter site complications
Severe Adverse Effects	Catheter related infection, respiratory tract infection, cytomegalovirus infection, vomiting, rash, hypersensitivity, anemia, immune thrombocytopenia, febrile neutropenia, pyrexia, electrolyte imbalance
Severe Drug-Drug Interactions	Vaccination with live virus vaccine not recommended until immune reconstitution is complete; do not use antiretrovirals for at least one month prior to mobilization until at least 7 days after infusion
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Negative pregnancy test must be confirmed prior to start of mobilization and re-confirmed before conditioning and infusion in females of childbearing potential; monitor complete blood count for cytopenias; monitor liver function tests during the first month after infusion
Used in Pediatric Areas	Safety and effectiveness not established in patients younger than 6 months
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity to active substance or any excipients; previous treatment with HSCT within 6 months prior to screening or HSCT with evidence of residual donor cells; previous treatment with hematopoietic stem cell gene therapy; or contraindications to the mobilization and conditioning regimen Warnings: hypersensitivity; engraftment failure; cytopenias; serious infections; transmission of an infectious agent; hepatic veno-occlusive disease; risk of oncogenesis; interference with HIV testing; future blood, organ, tissue, and cell donation
Special administration technique or considerations	Patients must undergo hematopoietic stem and progenitor cell mobilization followed by apheresis to obtain CD34+ cells for product manufacturing. Back-up supply should be retained for potential rescue treatment. Reduced intensity conditioning is required prior to administration. For autologous use only; prior to infusion confirm patient's identity matches the essential unique patient information on

	the infusion bag(s). Administer IV antihistamine 15-30 minutes prior to infusion. Administer using a central venous catheter. Flush bag and tubing with 0.9% sodium chloride solution to ensure as many cells as possible are infused. Monitor vital signs and for symptoms every 10 minutes during infusion and every hour, for 3 hours, after infusion.
Prepared by	Terri Levien
Source	Waskyra (etuvetidigene autotemcel) [prescribing information]. Rome, Italy: Fondazione Telethon ETS; December 2025.

Etripamil/Cardamyst/Milestone Pharmaceuticals USA	
Generic Name/Brand Name/Company	Etripamil/Cardamyst/Milestone Pharmaceuticals USA
Date of approval	12/12/25
Drug Class (Mechanism of Action if novel agent)	Calcium channel blocker
Indication	Conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults
Comparative agent – Therapeutic interchange?	IV adenosine, metoprolol, esmolol, verapamil, diltiazem, amiodarone
Dosage forms/strengths	Nasal spray: 70 mg per device
Common Dose/sig	Initial dose: 70 mg as two sprays, one in each nostril. If needed, a repeat dose of 70 mg administered as two sprays, one in each nostril, may be administered if symptoms persist for 10 minutes after the first dose.
DEA Schedule	N/A
Date of market availability	First quarter 2026
Similar Medication Names	Cardizem
Clinical Use Evaluation	
Common Adverse Effects	≥5%: nasal discomfort, nasal congestion, rhinorrhea, throat irritation, epistaxis
Severe Adverse Effects	Hypotension
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
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients.
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity, heart failure (NYHA class II to IV), Wolff-Parkinson-White or Lown-Ganong-Levine syndromes or manifest pre-excitation (delta wave) on 12-lead ECG, sick sinus syndrome (except in patients with a permanent pacemaker), or second degree atrioventricular Mobitz 2 block or higher degree of AV block Warnings: syncope – administer in sitting position
Special administration technique or considerations	Patients may self-administer. A 70 mg dose consists of two sprays, one in each nostril. Do not exceed 140 mg in a 24-hour period. Administer as soon as possible after PSVT symptom onset.
Prepared by	Terri Levien
Source	Cardamyst (Etripamil) [prescribing information]. Charlotte, NC: Milestone Pharmaceuticals USA; December 2025.

Lerodalcibep-liga/Lerochol/LIB Therapeutics	
Generic Name/Brand Name/Company	Lerodalcibep-liga/Lerochol/LIB Therapeutics
Date of approval	12/12/25
Drug Class (Mechanism of Action if novel agent)	PCSK9 inhibitor
Indication	Adjunct to diet and exercise to reduce LDL cholesterol in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia
Comparative agent – Therapeutic interchange?	Alirocumab, evolocumab
Dosage forms/strengths	Injection: 300 mg/1.2 mL in pre-filled syringe autoinjector
Common Dose/sig	300 mg subcutaneously once monthly
DEA Schedule	N/A
Date of market availability	Spring 2026
Similar Medication Names	Lercanidipine
Clinical Use Evaluation	
Common Adverse Effects	≥2%: injection site reactions, nasopharyngitis, diarrhea, nausea, peripheral edema
Severe Adverse Effects	None reported
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.	LDL-C
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustments required in mild to moderate renal or hepatic impairment; not studied in severe renal or hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications or warnings in the approved labeling
Special administration technique or considerations	Inject subcutaneously in the abdomen or thigh, or upper arm if administered by a caregiver or healthcare professional.
Prepared by	Terri Levien
Source	Lerodalcibep-liga (Lerochol) [prescribing information]. Cincinnati, OH: LIB Therapeutics; December 2025.

Zoliflodacin/Nuzolvence/La Jolla Pharmaceutical	
Generic Name/Brand Name/Company	Zoliflodacin/Nuzolvence/La Jolla Pharmaceutical
Date of approval	12/12/25
Drug Class (Mechanism of Action if novel agent)	Spiropyrimidimetrione bacterial type II topoisomerase inhibitor
Indication	Treatment of uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae in adults and pediatric patients 12 years and older, weighing at least 35 kg
Comparative agent – Therapeutic interchange?	Gepotidacin
Dosage forms/strengths	Oral suspension: 3 g in each unit-dose packet
Common Dose/sig	3 g (one packet) administered as a single oral dose
DEA Schedule	N/A
Date of market availability	Second half 2026
Similar Medication Names	Zolpidem, zoledronate
Clinical Use Evaluation	
Common Adverse Effects	≥2%: neutropenia, headache, leukopenia, dizziness, nausea, diarrhea
Severe Adverse Effects	diarrhea
Severe Drug-Drug Interactions	Moderate to severe CYP3A4 inducers: concomitant use is contraindicated due to potential reduction in zoliflodacin efficacy
Severe Drug-Food Interactions	Absorption is increased with administration with food
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy test in females of reproductive potential
Used in Pediatric Areas	No dosage adjustment in patients 12 years and older weighing at least 35 kg; safety and efficacy not established in pediatric patients younger than 12 years or weighing less than 35 kg
Renal or Hepatic Dosing	No dosage adjustments recommended
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: hypersensitivity, concomitant use with moderate or strong CYP3A4 inducers Warnings: Embryofetal toxicity risk in females of reproductive potential and males with female partners of reproductive potential: avoid use during pregnancy and advise males to use effective contraception for at least 3 months after zoliflodacin administration Testicular toxicity and potential risk to male fertility Hypersensitivity reactions Clostridioides difficile infection
Special administration technique or considerations	Mix with 60 mL of water before administration; do not mix with other liquids or sprinkle on food. Mix in provided mixing container and shake well for at least 60 seconds or until all granules are suspended and there is a uniform suspension. Administer entire dose within 15 minutes of mixing. Patients weighing 35 kg to less than 50 kg should take the dose on an empty stomach, 1 hour before or 2 hours after food. Patients weighing greater than 50 kg should take the dose with food. To ensure the full dose is consumed, an additional 60 mL of water should be added to the container, shaken, and ingested.
Prepared by	Terri Levien
Source	Nuzolvence (zoliflodacin) [prescribing information]. Waltham, MA: La Jolla Pharmaceutical; December 2025.

Depemokimab-ulaa/Exdensur/ GlaxoSmithKline	
Generic Name/Brand Name/Company	Depemokimab-ulaa/Exdensur/ GlaxoSmithKline
Date of approval	12/16/25
Drug Class (Mechanism of Action if novel agent)	Interleukin-5 antagonist monoclonal antibody
Indication	Add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients 12 years and older
Comparative agent – Therapeutic interchange?	Mepolizumab, reslizumab, benralizumab
Dosage forms/strengths	Injection: 100 mg/mL in single-dose prefilled syringe
Common Dose/sig	100 mg subcutaneously once every 6 months
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Depakote
Clinical Use Evaluation	
Common Adverse Effects	≥4%: upper respiratory tract infection, allergic rhinitis, influenza, arthralgia, pharyngitis
Severe Adverse Effects	None reported
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.	Serum IgE to confirm eosinophilic phenotype if not completed previously
Used in Pediatric Areas	Safety and efficacy not established in patients younger than 12 years
Renal or Hepatic Dosing	No dosage adjustments required
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: Hypersensitivity reactions Not for treatment of acute asthma symptoms or acute exacerbations Do not abruptly discontinue corticosteroids; reduce doses gradually Treat pre-existing helminth infections before initiating therapy
Special administration technique or considerations	Should be administered by a health care provider as a subcutaneous injection into the upper arm, thigh, or abdomen
Prepared by	Terri Levien
Source	Depemokimab-ulaa (Exdensur) [prescribing information]. Philadelphia, PA: GlaxoSmithKline; December 2025.

Aficamten/Myqorzo/Cytokinetics Incorpo	
Generic Name/Brand Name/Company	Aficamten/Myqorzo/Cytokinetics Incorpo
Date of approval	12/19/25
Drug Class (Mechanism of Action if novel agent)	Cardiac myosin inhibitor
Indication	Treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy to improve functional capacity and symptoms
Comparative agent – Therapeutic interchange?	Mavacamten
Dosage forms/strengths	Tablets: 5 mg, 10 mg, 15 mg, 20 mg
Common Dose/sig	Starting dose: 5 mg orally once daily; increase dose by 5 mg every 2 to 8 weeks until reach maintenance dose or maximum dose of 20 mg daily
DEA Schedule	N/A
Date of market availability	January 2026; through a REMS program due to heart failure risk
Similar Medication Names	Apixaban, MiCort
Clinical Use Evaluation	
Common Adverse Effects	Hypertension (8%)
Severe Adverse Effects	Heart failure
Severe Drug-Drug Interactions	Drugs that inhibit multiple pathways of aficamten elimination, strong CYP2C9 inhibitors, or moderate-to-strong CYP3A inducers: consult labeling for dosage adjustments
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	No required labs; perform ECG 2 to 8 weeks after initiation or any dose adjustment, on maintenance dose assess LVEF and Valsalva LVOT-G every 6 months, or every 3 months if LVEF is 50% to 55%, and as clinically indicated
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No routine dosage adjustments for renal or hepatic function required; the effects of severe renal or hepatic impairment have not been assessed.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: concomitant rifampin Warnings: Boxed warning: risk of heart failure – aficamten reduces left ventricular ejection fraction and can cause heart failure; assess ECG and avoid initiation in patients with LVEF less than 55%. Decrease dose if LVEF is less than 50% but remains 40% or greater; interrupt dosing if LVEF less than 40% or patient experiences symptoms due to systolic dysfunction. Serious intercurrent illness may increase risk of heart failure – consider decreasing dose or interrupting therapy during intercurrent illness Drug interactions
Special administration technique or considerations	Dose is adjusted based on LVEF and Valsalva LVOT-G. Administer orally with or without food at about the same time each day. Swallow tablets whole.
Prepared by	Terri Levien
Source	Myqorzo (aficamten) [prescribing information]. South San Francisco, CA: Cytokinetics Incorpo; December 2025.

Narsoplimab-wuug/Yartemlea/Omeros	
Generic Name/Brand Name/Company	Narsoplimab-wuug/Yartemlea/Omeros
Date of approval	12/23/25
Drug Class (Mechanism of Action if novel agent)	Monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), an enzyme of the lectin pathway of the complement system; MASP-2 inhibition is thought to prevent lectin-pathway-mediated cellular injury
Indication	Treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) in patients 2 years and older
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Injection: 370 mg/2 mL (185 mg/mL)
Common Dose/sig	≥50 kg: 370 mg as an IV infusion over 30 minutes once weekly; <50 kg: 4 mg/kg as an IV infusion over 30 minutes once weekly May increase to twice weekly if inadequate improvement
DEA Schedule	N/A
Date of market availability	January 2026 (projected)
Similar Medication Names	Yargesa, naratriptan, nivolumab, natalizumab, nerlimab
Clinical Use Evaluation	
Common Adverse Effects	(>20%): viral infections, sepsis, hemorrhage, diarrhea, vomiting, nausea, neutropenia, pyrexia, fatigue, hypokalemia
Severe Adverse Effects	Neutropenia, sepsis, pneumonia, hypokalemia, hypotension, anemia, hemorrhage, diarrhea, viral infection, vomiting, pyrexia, fatigue, nausea, abdominal pain
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.	Monitoring of platelet counts and LDH levels as markers of improvement
Used in Pediatric Areas	Patients 2 years and older; weight-based dosing for patients under 50 kg.
Renal or Hepatic Dosing	No routine dosage adjustments for renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: serious infections
Special administration technique or considerations	Do not co-administer other drugs in same IV line. Administer diluted in D5W through PVC or PVC-lined infusion line with 0.2 micron polyethersulfone (PES) in-line filter and a polyurethane catheter. Dilute to 0.8 mg/mL to 8 mg/mL for patients weighing 10 kg or more and administer via gravity infusion or infusion pump; for patients weighing less than 10 kg dilute to 0.8 mg/mL and administer via syringe pump. Flush line with D5W sufficient to clear the line.
Prepared by	Hayden Wesley
Source	Yartemlea (narsoplimab-wuuq) [prescribing information]. Seattle, WA: Omeros Corporation; December 2025.

Tradipitant/Nereus/Vanda Pharmaceuticals	
Generic Name/Brand Name/Company	Tradipitant/Nereus/Vanda Pharmaceuticals
Date of approval	12/30/25
Drug Class (Mechanism of Action if novel agent)	Neurokinin-1 (NK-1) receptor antagonist
Indication	Motion sickness prophylaxis in adults
Comparative agent – Therapeutic interchange?	Scopolamine patch, meclizine, dimenhydrinate
Dosage forms/strengths	Capsules: 85 mg
Common Dose/sig	1 or 2 capsules as a single oral dose approximately 1 hour before event expected to cause motion sickness.
DEA Schedule	N/A
Date of market availability	By mid 2026
Similar Medication Names	Aprepitant, neratinib, Nerlynx
Clinical Use Evaluation	
Common Adverse Effects	(≥5%): somnolence, headache, fatigue
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Tradipitant is a CYP3A4 substrate. Strong CYP3A4 inhibitors may increase tradipitant concentration and adverse events.
Severe Drug-Food Interactions	High fat meals may increase concentration of drug significantly, potentially increasing side effects. Must be taken on an empty stomach.
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 dose adjustment in mild to moderate renal impairment. Avoid use in severe renal dysfunction or any Child-Pugh class hepatic dysfunction.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Warnings: may impair mental and/or physical abilities; counsel patients to learn how this medication affects them before driving or operating heavy machinery. Do not take concomitantly with other drugs that may cause CNS depression or with strong CYP3A4 inhibitors. Or, if concomitant use is necessary, counsel patients to avoid driving and operating heavy machinery as mental alertness is likely to be diminished. Advise breastfeeding women using tradipitant to monitor infants for somnolence and to seek medical care if somnolence is observed.
Special administration technique or considerations	Must be taken on an empty stomach 1 hour prior to or 2 hours after a full meal.
Prepared by	Hayden Wesley
Source	Nereus (Tradipitant) [prescribing information]. Washington, D.C.: Vanda Pharmaceuticals; December 2025.