



Highlights of FDA Activities – 5/1/26 – 5/31/26

FDA Drug Safety Communications & Drug Information Updates:

Product	Description	Date
Expanded Access for Investigational Pancreatic Cancer Drug, Daraxonrasib	The FDA is allowing Revolution Medicines to initiate an expanded access treatment protocol for daraxonrasib, an investigational RAS inhibitor for the treatment of metastatic pancreatic ductal adenocarcinoma. The manufacturer plans to submit a new drug application for the drug under a national priority voucher.	5/1/26
Tazverik (tazemetostat): Increased Risk of New Blood Cancers – Withdrawal from Market	Tazemetostat is being voluntarily withdrawn from the market due to an increased rate of hematologic second primary malignancies.	5/11/26
Levonorgestrel 1.5 mg, Amazon Basic Care: Delivered Past Expiration Date – Avoid Use	The FDA advised consumers not to use expired levonorgestrel 1.5 mg from Amazon Basic Care. Several lots of the product were delivered to purchasers past the labeled expiration date. Distribution occurred between 1/24/25 and 4/29/26. Consumers should be advised to check labels and discard product if the expiration date is passed. Consumers who used expired product should contact their health care professional to determine the best course of action.	5/15/26

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

Product	Description	Date
TRUE METRIX Blood Glucose Monitoring Systems, Trividia Health: Correction – Error Codes	Trividia Health updated the labeling correction announced in February 2026 for all TRUE METRIX, TRUE METRIX AIR, TRUE METRIX GO, and TRUE METRIX PRO blood glucose monitoring systems to advise users with diabetes to consider transitioning to an alternative testing method and to ensure all patients continuing to use the products are aware that if they see an E-5 Error Code (indicating either a very high blood glucose or test strip error) they should retest with a new test strip. If the error persists and they are experiencing symptoms they should seek immediate medical attention.	5/5/26
MG217 Multi-Symptom Treatment Cream & Skin Protectant Eczema Cream, Pharmacal: Recall – Microbial Contamination	Pharmacal recalled one lot of MG217 Multi-Symptom Treatment Cream & Skin Protectant Eczema Cream, 6 oz tube (product code 5106; UPC 012277051067) due to contamination with <i>Staphylococcal aureus</i> .	5/13/26

DOXOrubicin Hydrochloride Liposome Injection 50 mg/25 mL, Sun Pharma: Recall – Presence of Glass Particles	Sun Pharma recalled one batch of DOXOrubicin hydrochloride liposome injection 50 mg/25 mL (Lot# HAG2581B, Expiration 05/2027) to the user level due to the detection of glass particles in some vials.	5/14/26
Namic Manifolds, Medline: Recall – Particulate Within Fluid Path	Medline recalled Namic Angiographic Manifold, Namic Preceptor Manifold, Namic Compensator Manifold, and Medline Convenience Kits containing Namic Manifolds due to the presence of particulate within the fluid path which has the potential to be introduced into blood circulation. These manifolds are used for fluid management, contrast media, and pressure monitoring. A full list of affected products can be found on a link at the FDA site . Affected manifolds must be removed from use and discarded.	5/26/26
Omnipod Pods, Insulet: Medical Device Correction – Under Delivery of Insulin	Insulet Corporation issued a Medical Device Correction for specific lots of Omnipod 5, Omnipod DASH, and Omnipod Insulin Management System (Omnipod Eros) pods due to a manufacturing issue that could result in under delivery of insulin. Pods from affected lots should be replaced. If an affected pod is currently in use, customers should discontinue use and replace it with a pod from an unaffected lot.	5/26/26
IV Tubing Set, ICU Medical: Early Alert – Inspect for Compromise	ICU Medical issued a communication and the FDA issued an early alert following reports of anomalies, including marks or black specks on the chamber walls and particulate matter within the drip chambers of certain IV tubing sets. Users should inspect all IV tubing sets for any evidence of compromise including marks or specks on the chamber walls, particulate matter in the drip chamber or fluid path, and condensation within the device. If sets with anomalies are found, users should segregate the sets, complete a MedWatch complaint, and contact ICU Medical for returns.	5/27/26
Dexcom G7 Sensors, DexCom: Recall – Third Party Sale of Product Not Meeting Specifications	DexCom and the FDA notified users of Dexcom G7 continuous glucose monitoring systems that two sensor lots did not meet specifications and were designated as scrap but were stolen prior to destruction and have been sold. Pharmacies who purchased product from PharmSource, who is not an authorized vendor for Dexcom, should review their inventory. Users with affected Dexcom G7 lots (#1725204004 and #1725069002) should not use those lots. Lot #1725204004 was not properly sterilized and could have increased risk of skin infection. Lot #1725069002 had an elevated internal testing failure rate and has increased risk of having no sensor readings available.	5/29/26

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
a2 Platinum Premium USA infant formula*	Infant formula	Cereulide ¹
Baiphong Herbs Tea Drink	Pain	Piroxicam
Better Weather Fix Elixir Products*	Herbal supplement	Mitragynine, mitragynine pseudoindoxyl ²
Big Dick Energy!	Sexual enhancement	Tadalafil
biQ-FEL	Sexual enhancement	Sildenafil, tadalafil
Boner Bears Chocolate by JXK Enterprises*	Sexual enhancement	Sildenafil
Doctor's Pride Complete Green Superfood Ultra Potent Moringa 10,000 mg*	Herbal supplement	Salmonella
Erectus Plus	Sexual enhancement	Sildenafil, tadalafil, testosterone propionate
Hard AF!	Sexual enhancement	Sildenafil, tadalafil
Mogo Moringa Oleifera Capsules*	Herbal supplement	Salmonella
RAPTURE Preworkout	Boost energy and increase performance	1,3-dimethylamylamine (DMAA) ³
Sâm Xương Khớp Ông Tiên	Joint/bone pain relief	Dexamethasone phosphate, piroxicam
Sensual Miracle Honey	Sexual enhancement	Sildenafil, tadalafil
Tawon Liar	Pain, rheumatism, insomnia, immune system improvement, increasing energy, lowering cholesterol	Tapentadol, dexamethasone, meloxicam
TNVitamins Ultra Potent Complete Green Superfood Moringa 10,000 mg*	Herbal supplement	Salmonella
WAP Sensual Enhancement Capsules*	Sexual enhancement	Sildenafil, tadalafil, flibanserin
X10 Natural Enhancement Supplement	Sexual enhancement	Sildenafil, tadalafil

*recalled

¹toxin produced by *Bacillus cereus*

²mitragynine is the primary psychoactive alkaloid found in kratom, mitragynine pseudoindoxyl is a more potent derivative of mitragynine

³also known as "geranium extract", DMAA can increase blood pressure potentially leading to adverse cardiovascular events

New Product Shortages (per FDA or ASHP)

Product	Date Initially Posted
Iohexol injection	5/5/26
Flumazenil injection	5/13/26
Progesterone capsules	5/14/26
RimabotulintoxinB intramuscular injection	5/22/26

[ASHP Drug Shortages List](#) contains up-to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals

Product	Date Posted
Sulconazole nitrate solution (Exelderm, Journey Medical): cream remains available	5/8/26
Activated charcoal oral suspension (Actidose and Actidose Aqua, Padagis): oral suspension remains available from other manufacturers	5/15/26
Alteplase (Activase, Genentech): 100 mg vial; other configurations remain available	5/21/26

New Drug Approvals

Product	Description (See Attached Drug Summaries)	Date Approved
Vepdegestrant/Veppanu/Arvinas	Heterobifunctional protein degrader for the treatment of adult patients with estrogen receptor positive, HER2-negative, ESRI-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	5/1/26
Sonrotoclax/Beqalzi/BeOne Medicines USA	BCL-2 inhibitor for the treatment of adults with relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a Bruton's tyrosine kinase inhibitor	5/13/26
Baxdrostat/Baxfendy/AstraZeneca	Aldosterone synthase inhibitor for the treatment of hypertension in combination with other agents	5/15/26
Bulevirtide-gmod/Hepcludex/Gilead	Hepatitis D virus attachment inhibitor for the treatment of chronic hepatitis D virus infection in adults without cirrhosis or with compensated cirrhosis	5/22/26
Pivekimab sunirine-pvzy/Decnupaz/AbbVie	CD123-directed antibody and alkylating agent conjugate for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm	5/27/26
Cefepime and zidebactam/Zaynich/Wodkhardt	Cephalosporin antibacterial and beta-lactamase inhibitor/non-beta-lactam antibacterial for the treatment of adults with complicated urinary tract infections including pyelonephritis	5/29/26

Product	Description (See Attached Drug Summaries)	Date Approved
Cipepofol/Cypsedo/Haisco Pharmaceutical Group	General anesthetic (propofol analog) to induce general anesthesia in adults undergoing surgery; FDA-approved labeling is not available. Cipepofol was developed and has been available in China for several year but marketing plan in the US is not known.	5/29/26
Ensitrelvir/Xocova/Shionogi Inc	SARS-CoV-2 main protease inhibitor for post-exposure prophylaxis of COVID-19 following contact with an individual who has COVID-19	5/29/26

New Indications

Product	Description	Date Approved
Immune globulin intravenous, human-sIra/Asceniv/ADMA Biologics	Primary humoral immunodeficiency indication expanded to include pediatric patients 2 years and older	5/4/26
Efgartigimod alfa-fcab/Vyvgart/argenx US	Indication expanded to treatment of generalized myasthenia gravis in adult patients; qualifiers have been removed	5/8/26
Efgartigimod alfa and hyaluronidase-qvfc/Vyvgart Hyrtulo/argenx US	Indication expanded to treatment of generalized myasthenia gravis in adult patients; qualifiers have been removed	5/8/26
Ocrelizumab/Ocrevus/Genetech	Indication expanded to include treatment of relapsing-remitting multiple sclerosis in pediatric patients 10 years of age and older who weigh at least 25 kg	5/8/26
Zenocutuzumab-zbco/Bizengri/ Partner Therapeutics	Treatment of adults with advanced unresectable or metastatic cholangiocarcinoma harboring a neuregulin 1 gene fusion with disease progression on or after prior systemic therapy	5/8/26
Ceftolozane and tazobactam/Zerbaxa/Cubist Pharmaceuticals	Indication expanded to include treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia in pediatric patients at least 32 weeks gestational age and older	5/12/26
Decitabine and cedazuridine/Inqovi/ Taiho Oncology	In combination with venetoclax for treatment of newly diagnosed acute myeloid leukemia in adults 75 years or older, or who have comorbidities that preclude the use of intensive induction chemotherapy	5/13/26
Benralizumab/Fasenra/AstraZeneca	Treatment of adult and pediatric patients 12 years and older with hypereosinophilic syndrome without an identifiable non-hematologic secondary cause	5/13/26

Product	Description	Date Approved
Fam-trastuzumab deruxtecan-nxki/Enhertu/AstraZeneca and Daiichi Sankyo	In the adjuvant setting, approved for the treatment of adult patients with HER2-positive breast cancer who have residual invasive disease following trastuzumab (with or without pertuzumab) and taxane-based treatment	5/15/26
Fam-trastuzumab deruxtecan-nxki/Enhertu/AstraZeneca and Daiichi Sankyo	In the neoadjuvant setting, approved followed by a taxane, trastuzumab, and pertuzumab for the treatment of adult patients with HER2-positive Stage II or Stage III breast cancer	5/15/26
Atezolizumab/Tecentriq/Genentech	As adjuvant treatment for adults with muscle invasive bladder cancer after cystectomy who have circulating tumor DNA molecular residual disease	5/15/26
Atezolizumab and hyaluronidase-tqjs/Tecentriq Hybreza/Genentech	As adjuvant treatment for adults with muscle invasive bladder cancer after cystectomy who have circulating tumor DNA molecular residual disease	5/15/26
Linaclotide/Linzess/AbbVie	Indication expanded to include use in the treatment of functional constipation in pediatric patients 2 years and older	5/21/26
Datopotamab deruxtecan/Datroway/Daiichi Sankyo	Treatment of adult patients with unresectable or metastatic triple-negative breast cancer who are not candidates for PD-1/PD-L1 inhibitor therapy	5/22/26
Adapalene 0.1% and benzyl peroxide 2.5%/Differin Epiduo Acne Gel/Galderma	Approved for use over-the-counter for the treatment of acne in adults and children 12 years and older	5/22/26
Selexipag/Upravi/Actelion	Treatment of pulmonary arterial hypertension (WHO Group 1) in pediatric patients 2 years and older to delay disease progression and reduce hospitalization risk	5/23/26
Durvalumab/Imfinzi/AstraZeneca	In combination with BCG for the treatment of adult patients with BCG-naïve, high-risk, non-muscle-invasive bladder cancer	5/28/26
Insulin human/Afrezza/Mannkind	Use in children 6 years and older with type 1 and type 2 diabetes	5/29/26

New Dosage Forms or Formulation

Product	Description	Date Approved
Trabectedin/Evdi/Apotex	Injection: 1 mg/20 mL solution; for the treatment of adult patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen	5/1/26
Ruxolitinib/Jakafi XR/Incyte	Extended-release tablets: 11 mg, 22 mg, 33 mg, 44 mg, 55 mg; administered once-daily for treatment of	5/1/26

Product	Description	Date Approved
	intermediate or high-risk myelofibrosis, polycythemia vera in adults with an inadequate response or intolerance to hydroxyurea, steroid-refractory acute graft-versus-host disease, and chronic graft-versus-host disease after failure of one or two lines of systemic therapy	
Beclomethasone dipropionate, formoterol, and glycopyrrolate/ Trimbow/Cheisi USA	Inhalation aerosol: 86 mcg/4.9 mg/10.6 mcg and 172 mcg/4.9 mcg/10.6 mcg per actuation; for maintenance treatment of asthma in adults	5/14/26

Compiled by:

Terri Levien, Pharm.D.
Hayden Wesley, Pharm.D.

Dr Danial Baker Drug Information and Telehealth 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

New Drug Approvals: Drug Summaries

Vepdegestrant/Veppanu/Arvinas Operations, Inc.

Date of approval	5/1/26
Drug Class/Mechanism of Action	Heterobifunctional protein degrader
Indication	Treatment of adult patients with estrogen receptor positive, HER2-negative, ESRI-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy
Comparative agent	Orserdu (elacestrant)
Dosage forms/strengths	Tablet: 100 mg, 200 mg
Common Dose/sig	200 mg by mouth twice daily with food
DEA Schedule	NA
Date of market availability	To be determined
Similar Medication Names	Venlafaxine, Ventolin, verapamil, Vesprin

Clinical Use Evaluation

Common Adverse Effects ($\geq 10\%$)	Musculoskeletal pain (30%), fatigue (29%), nausea (14%), decreased appetite (11%), QTc prolongation (10%), constipation (10%)
Severe Adverse Effects	QT prolongation, musculoskeletal pain
Severe Drug-Drug Interactions	Strong CYP3A inhibitors: avoid or reduce vepdegestrant dose; strong CYP3A inducers: avoid or increase vepdegestrant dose; certain P-gp or UGT1A9 substrates: avoid use with substrates where serious side effects may occur with just minimal concentration increases
Severe Drug-Food Interactions	Avoid: St. John's Wort, grapefruit, grapefruit juice
Important Lab Monitoring	Electrolytes
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild to moderate renal impairment or mild hepatic impairment; not studied in severe renal impairment or moderate to severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: no labeled contraindications Warnings: QT prolongation – monitor ECG and electrolytes; correct hypokalemia and hypomagnesemia Embryo-fetal toxicity – advise use of effective contraception
Special administration technique or considerations	Take with food. Do not crush, chew, split, dissolve, or take tablets that are broken or appear damaged. Dosage modifications may be made per package insert for various adverse reactions, including QTc prolongation.
Source	Veppanu (vepdegestrant) [prescribing information]. New York City, NY: Arvinas Operations, Inc; May 2026.

Sonrotoclax/Beqalzi/BeOne Medicines USA

Date of approval	5/13/26
Drug Class/Mechanism of Action	B-cell lymphoma (BCL)-2 inhibitor
Indication	Treatment of adults with relapsed or refractory mantle cell lymphoma after at least two lines of systemic therapy, including a Bruton's tyrosine kinase inhibitor
Comparative agent	Venetoclax (used off-label in mantle-cell lymphoma)
Dosage forms/strengths	Tablets: 1 mg, 5 mg, 20 mg, 80 mg
Common Dose/sig	320 mg orally once daily following 4-week dose ramp-up schedule
DEA Schedule	NA
Date of market availability	To be determined
Similar Medication Names	Beqvez

Clinical Use Evaluation

Common Adverse Effects	Pneumonia (16%), fatigue (16%), grade 3 or 4 decreased lymphocytes (29%) or neutrophils (18%)
Severe Adverse Effects	Infections, tumor lysis syndrome, neutropenia
Severe Drug-Drug Interactions	Strong CYP3A inhibitors contraindicated at initiation and dosing ramp-up; moderate CYP3A inhibitors: avoid use with 1 and 2 mg doses and reduce all other doses; strong or moderate CYP3A inducers: avoid use
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Blood counts
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild or moderate hepatic or renal impairment; has not been studied in severe hepatic or renal impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: concomitant strong CYP3A inhibitors Warnings: tumor lysis syndrome – assess risk and premedicate Serious infections – monitor Neutropenia – monitor blood counts regularly Embryo-fetal toxicity – advise use of effective contraception
Special administration technique or considerations	Initiate prophylactic hydration and anti-hyperuricemics before first dose. Consult labeling for ramp-up schedule and dosing adjustments for adverse events, drug interactions, and dosing interruptions. Administer with a meal once daily at the same approximate time.
Source	Beqalzi (sonrotoclax) [prescribing information]. Pennington, NJ: BeOne Medicines USA Inc; May 2026.

Baxdrostat/Baxfendy/AstraZeneca

Date of approval	5/15/26
Drug Class/Mechanism of Action	Aldosterone synthase inhibitor
Indication	Treatment of hypertension in combination with other antihypertensive drugs in adults not adequately controlled on other agents
Comparative agent	None
Dosage forms/strengths	Tablets: 1 mg, 2 mg
Common Dose/sig	2 mg orally once daily
DEA Schedule	NA
Date of market availability	June 9, 2026
Similar Medication Names	Baxdela

Clinical Use Evaluation

Common Adverse Effects	Hyperkalemia (10%), hypotension (4%), hyponatremia (3%), dizziness (3%), muscle spasms (3%)
Severe Adverse Effects	None reported
Severe Drug-Drug Interactions	Drugs that increase serum potassium: monitor serum potassium; strong and moderate CYP3A inducers: monitor therapeutic effect
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Serum potassium and sodium prior to initiation and periodically during therapy
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in patients with eGFR >45 mL/min unless at risk for hyperkalemia. Safety and efficacy have not been established in patients with eGFR < 45 mL/min, although pharmacokinetics were not altered. Pharmacokinetics were not altered in mild to moderate hepatic impairment; has not been studied in severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: no labeled contraindications Warnings: Hyperkalemia – monitor Hyponatremia – monitor
Special administration technique or considerations	Reduce dose in patients at increased risk for hyperkalemia or hyponatremia
Source	Baxfendy (baxdrostat) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.

Bulevirtide-gmod/Hepcludex/Gilead

Date of approval	5/22/26
Drug Class/Mechanism of Action	Sodium taurocholate co-transporting polypeptide-directed hepatitis D virus attachment inhibitor
Indication	Treatment of chronic hepatitis D virus infection in adults without cirrhosis or with compensated cirrhosis
Comparative agent	None
Dosage forms/strengths	Injection: 8.5 mg as lyophilized powder in single-dose vial
Common Dose/sig	8.5 mg subcutaneously once daily for as long as there is a response
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Dulaglutide, Hepclisav

Clinical Use Evaluation

Common Adverse Effects	Injection site reactions (30%), headache (20%), abdominal pain (18%), fatigue (14%), pruritus (14%)
Severe Adverse Effects	Anaphylaxis
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Lab Monitoring	HDV RNA viral load and ALT for response on therapy; HBV DNA and HDV RNA viral loads and hepatic function following discontinuation
Used in Pediatric Areas	Safety and efficacy have not been established
Renal or Hepatic Dosing	No dosage adjustment in mild, moderate, or severe renal impairment or mild hepatic impairment; has not been studied in moderate or severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: none in labeling Boxed warning: following bulevirtide discontinuation, severe acute exacerbations of hepatitis D and hepatitis B may occur Warnings: Exacerbation after discontinuation Hypersensitivity reactions, including anaphylaxis
Special administration technique or considerations	Patients may self-administer following training. Reconstitute with 1 mL sterile water for injection. Administer subcutaneously into upper thigh, lower abdomen, or back of upper arm (if by caregiver).
Source	Hepcludex (bulevirtide-gmod) [prescribing information]. Foster City, CA: Gilead Sciences Inc; May 2026.

Pivekimab sunirine-pvzy/Decnupaz/AbbVie

Date of approval	5/27/26
Drug Class/Mechanism of Action	CD123-directed antibody and alkylating agent conjugate
Indication	Treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm
Comparative agent	None
Dosage forms/strengths	Injection: 2 mg as lyophilized cake in single-dose vial
Common Dose/sig	0.045 mg/kg IV every 3 weeks
DEA Schedule	NA
Date of market availability	Available
Similar Medication Names	Pivmecillinam, sunitinib

Clinical Use Evaluation

Common Adverse Effects	Edema (52%), fatigue (34%), musculoskeletal pain (34%), hemorrhage (28%), infusion-related reactions (26%), nausea (24%), diarrhea (21%), grade 3 or 4 laboratory abnormalities (>10%): decreased neutrophils, platelets, lymphocytes, white blood cells, hemoglobin, increased glucose
Severe Adverse Effects	Edema, fatigue, febrile neutropenia, hemorrhage, hepatotoxicity, infections, infusion-related reactions, musculoskeletal pain, thrombosis
Severe Drug-Drug Interactions	Strong and moderate CYP3A inhibitors: monitor for adverse reactions
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Liver function tests: ALT, AST, total bilirubin
Used in Pediatric Areas	Safety and efficacy have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment in mild hepatic or renal impairment; avoid use in moderate or severe hepatic or renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: no labeled contraindications Boxed warning: hepatotoxicity including hepatic veno-occlusive disease Warnings: Infusion-related reactions – premedicate and monitor Edema – monitor Sulfite allergic reaction – contains sodium metabisulfite Embryo-fetal toxicity – advise use of effective contraception
Special administration technique or considerations	Administer as IV infusion at a rate of 0.8 mL/min for the first 30 minutes and then increase to 1.7 mL/min if tolerated; subsequent infusions may be administered at the highest tolerated rate. Premedicate with an oral or IV corticosteroid one day prior to infusion and with an IV corticosteroid, IV antihistamine, and an oral antipyretic at least 30 to 60 minutes before infusion. Monitor for infusion reactions during infusion and for at least 4 hours after the first infusion and for at least 1 hour after subsequent infusions. Hazardous drug requires special handling/disposal procedures.
Source	Decnupaz (pivekimab sunirine-pvzy) [prescribing information]. North Chicago, IL: AbbVie Inc; May 2026.

Cefepime and zidebactam/Zaynich/ Wodkhardt

Date of approval	5/29/26
Drug Class/Mechanism of Action	Cephalosporin antibacterial and beta-lactamase inhibitor/non-beta-lactam antibacterial
Indication	Treatment of adults with complicated urinary tract infections including pyelonephritis caused by the following susceptible microorganisms: <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Proteus mirabilis</i> , <i>Enterobacter cloacae</i> complex, and <i>Pseudomonas aeruginosa</i>
Comparative agent	Ceftolozane and tazobactam, ceftazidime and avibactam
Dosage forms/strengths	Injection: 3 g (cefepime 2 g/zidebactam 1 g) powder in a single-dose vial
Common Dose/sig	3 g every 8 hours by IV infusion over 1 hour for 7 to 10 days
DEA Schedule	N/A
Date of market availability	Late 2026/early 2027; currently available via expanded access program
Similar Medication Names	Cefepime, Zantac

Clinical Use Evaluation

Common Adverse Effects	Diarrhea (4%), headache (3%), hypertension (3%), hypokalemia (3%)
Severe Adverse Effects	Anaphylaxis, hypersensitivity, neurotoxicity, <i>Clostridioides difficile</i> colitis
Severe Drug-Drug Interactions	Aminoglycosides or diuretics: monitor renal function
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Renal function
Used in Pediatric Areas	Safety and efficacy have not been established
Renal or Hepatic Dosing	Adjustments required for eGFR less than 60 mg/mL (eGFR 30-59: 1.5 g every 8 hrs; eGFR 15-29: 1.5 g every 12 hrs; eGFR 8-14: 1.5 g every 24 hrs); no adjustments in hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: known hypersensitivity to components or other beta-lactam antibacterial drugs Warnings: Hypersensitivity reactions Neurotoxicity <i>C. difficile</i> infection
Special administration technique or considerations	Administer IV as infusion over 1 hour.
Source	Zaynich (cefepime and zidebactam) [prescribing information]. Newark, DE: Wockhardt Suisse USA LLC; May 2026.

Ensitrelvir/Xocova/Shionogi Inc

Date of approval	5/29/26
Drug Class/Mechanism of Action	SARS-CoV-2 main protease inhibitor antiviral
Indication	Post-exposure prophylaxis of COVID-19 in adults and adolescents 12 years and older following contact with an individual who has COVID-19
Comparative agent	None
Dosage forms/strengths	Tablets: 125 mg
Common Dose/sig	375 mg (3 tablets) orally on day 1 and 125 mg (1 tablet) orally on days 2-5
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Ensifentrine, Enstilar, Xofluza

Clinical Use Evaluation

Common Adverse Effects	Headache (3%), diarrhea (2%), cough (1%)
Severe Adverse Effects	Hypersensitivity
Severe Drug-Drug Interactions	Ensitrelvir is a strong CYP3a inhibitor and an inhibitor of P-gp and BCRP; review all medications to assess for drug interactions
Severe Drug-Food Interactions	None known
Important Lab Monitoring	Verify pregnancy status
Used in Pediatric Areas	Safety and efficacy not established in patients younger than 12 years
Renal or Hepatic Dosing	No dosage adjustment in renal impairment or mild to moderate hepatic impairment; not studied in severe hepatic impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	<p>Contraindications: hypersensitivity, co-administration with drugs metabolized by CYP3A for which elevated concentrations may be associated with serious reactions, co-administration with strong CYP3A inducers</p> <p>Warnings:</p> <ul style="list-style-type: none"> Embryofetal toxicity – advise use of effective contraception Drug interactions Hypersensitivity reactions
Special administration technique or considerations	Initiate as soon as possible and within 72 hours following contact with an individual with COVID-19. On day 1 take 3 tablets at the same time; doses should be taken at approximately same time each day. Doses can be taken with or without food.
Source	Xocova (ensitrelvir) [prescribing information]. Florham Park, NJ: Chionogi Inc; May 2026.