Keeping Up-to-Date, with so little time: Newly Approved Medications Review 2026

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Disclosures and Conflict of Interest

- Golden Peters & Erin Hennessey declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.

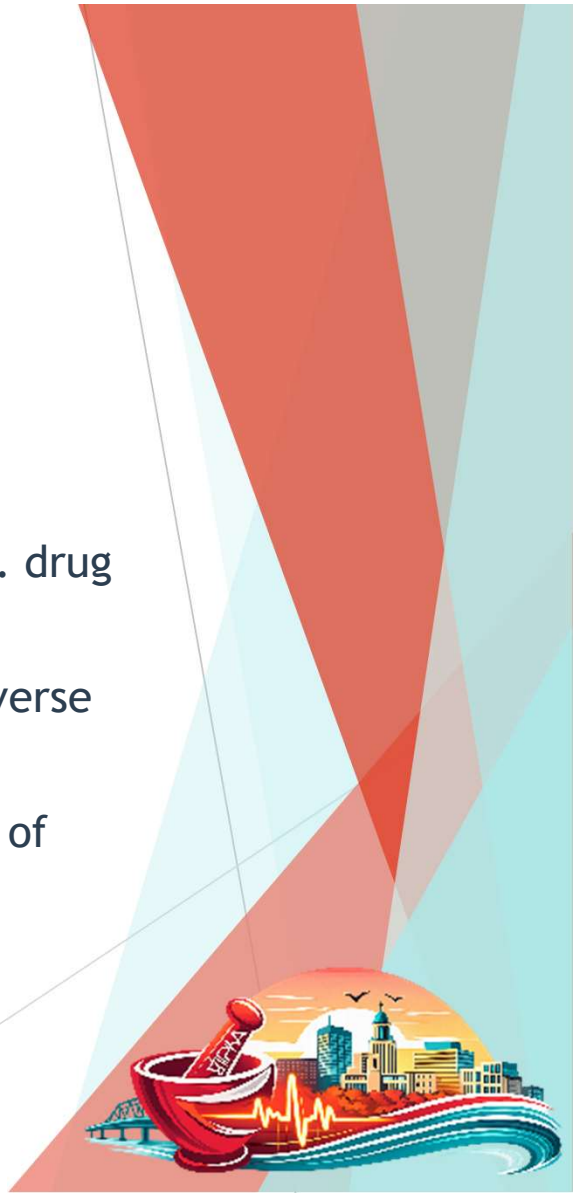
Disclosure of AI Use

- AI was not used in development of this presentation.

Pharmacist Objectives

At the conclusion of this program, the pharmacist will be able to:

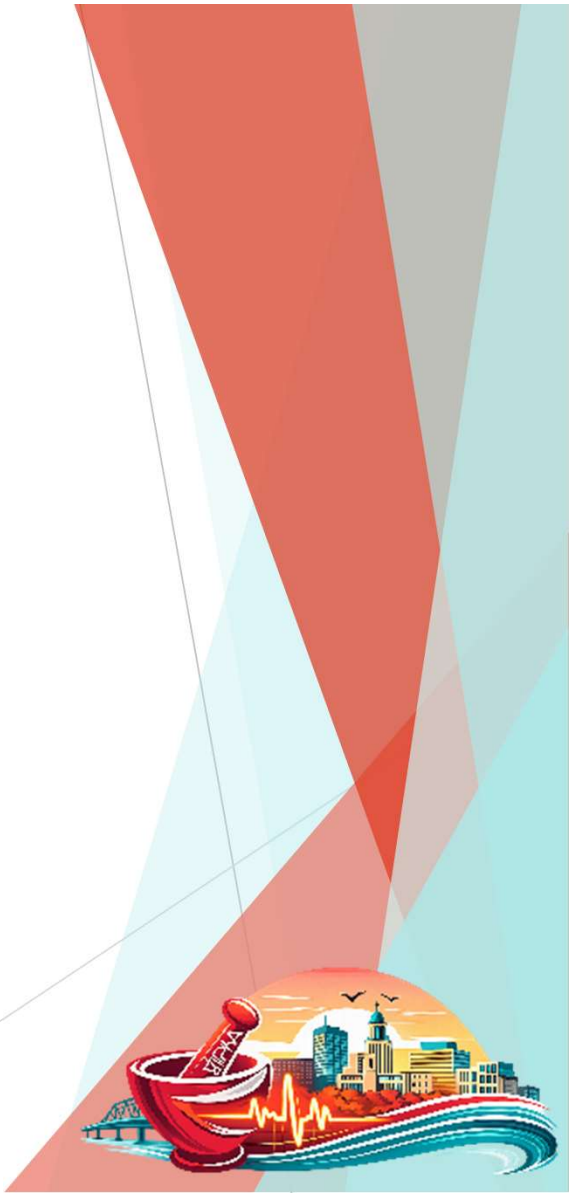
- Identify new molecular and biological entities that entered the U.S. drug market in the past year (excluding diagnostic compounds)
- Describe each agent's indication, mechanism of action, dosage, adverse reactions, contraindications, and drug interaction profile
- List special patient instruction and monitoring parameters for each of these agents
- Identify molecular entities that have been approved as generic medications by the FDA in the past year



Technician Objectives

At the conclusion of this program, the technician will be able to:

- Recognize novel drugs approved by the FDA in the past 12 months
- Recall each agent's indication, dosage, major adverse reactions, contraindications, and major drug interactions
- Identify special patient education/instructions for each agent
- Recall medications that have been approved as generic medications by the FDA in the past year



Which newly approved medication has hyperkalemia listed as its most common adverse reaction?

A. Zoliflodacin
B. Baxdrostat
C. Tradipitant
D. Elinzanetant

Pre-Test Question #1

Which newly approved medication requires monitoring of liver function tests before initiation and during therapy?

A. Orforglipron
B. Etripamil
C. Elinzanetant
D. Insulin icodec-abae

Pre-Test Question #2

Which newly approved medication is FDA approved to treat vomiting associated with motion?

A. Milsaperidone
B. Zoliflodacin
C. Tradipitant
D. Doravirine/Islatravir

Pre-Test Question #3

Which medication recently became available as a generic in the United States?

A. Apixaban
B. Edoxaban
C. Canagliflozin
D. Tapentadol extended-release

Pre-Test Question #4

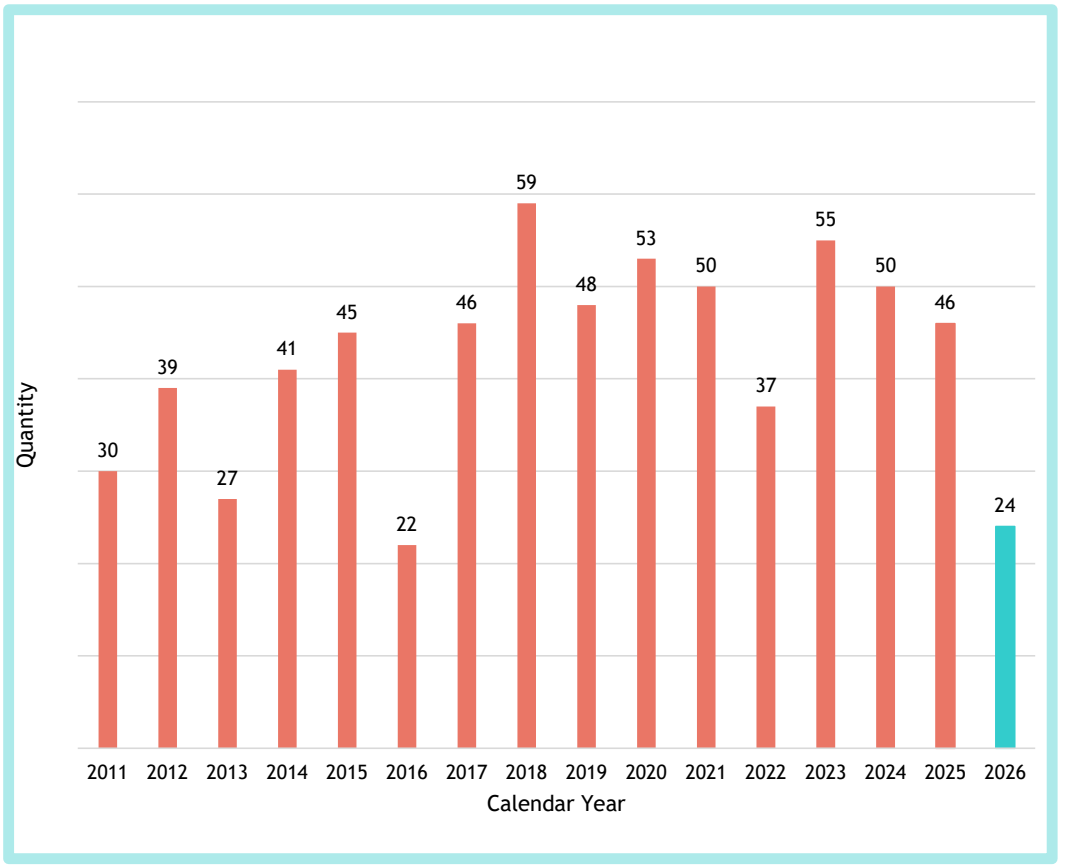
CYP450 Substrates

3A4 inhibitors	3A4 inducers	2D6 inhibitors	1A2 substrates
Amiodarone	Carbamazepine	Amiodarone	Caffeine
Cimetidine	Oxcarbazepine	Bupropion	Clozapine
Clarithromycin	Phenobarbital	Chloroquine	Frovatriptan
Diltiazem	Phenytoin	Diphenhydramine	Mirtazapine
Erythromycin	Pioglitazone	Fluoxetine	Olanzapine
Grapefruit juice	Rifampin	Haloperidol	Ramelteon
Ketoconazole	St. John's Wort	Paroxetine	Rasagiline
Verapamil	Topiramate	Terbinafine	Ropinirole
			Triamterene
			Zolmitriptan

Lexi-Comp, Inc. (Lexi-Drugs®). Lexi-Comp, Inc.; June 25, 2025.

CDER's Annual Novel Drug Approvals (2011-2025)

- In 2025, CDER approved novel drugs. This graph shows that from 2011-2025, CDER has averaged about 43 novel drug approvals per year.
- **To date in 2026 → 29**

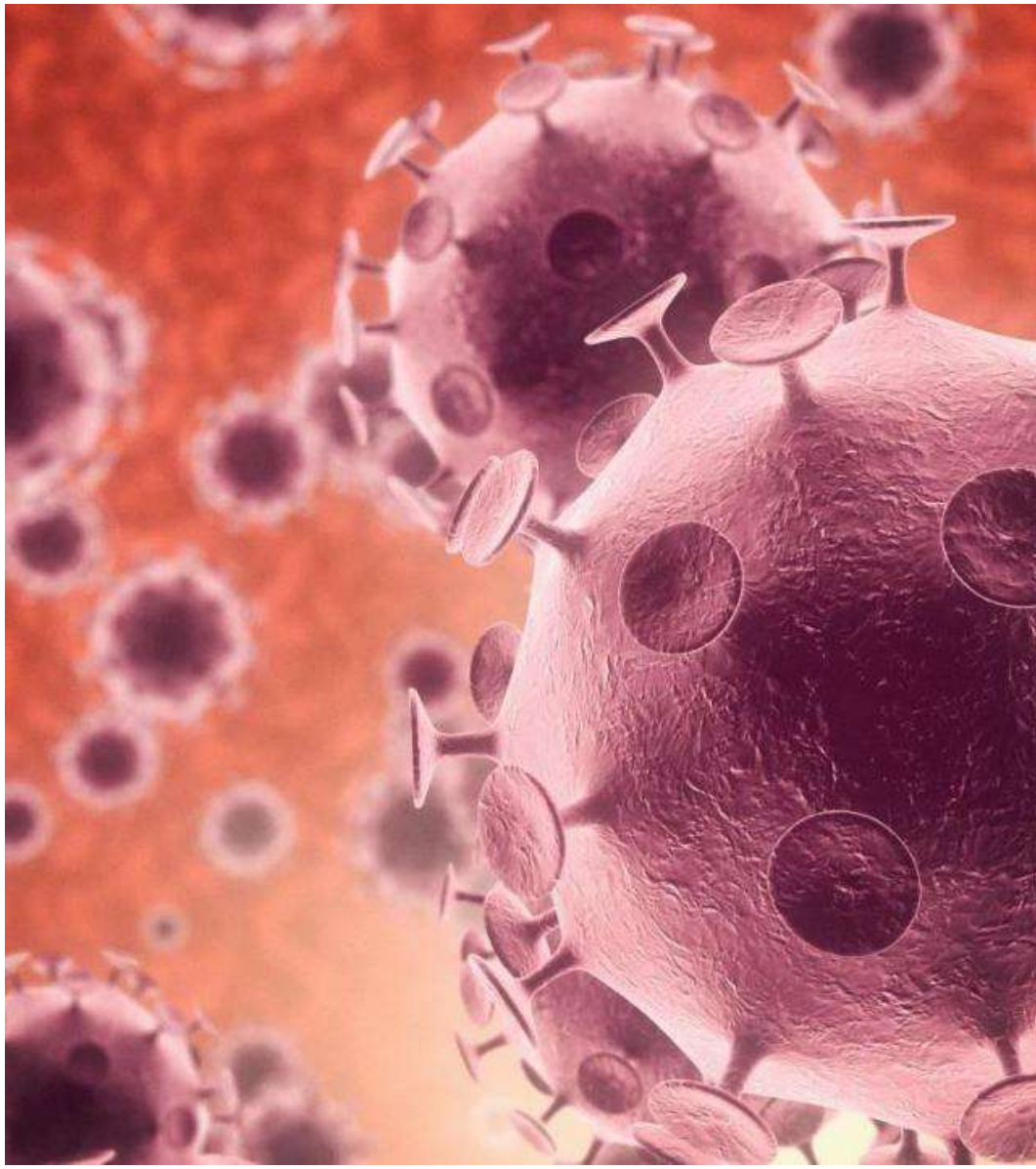


https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2020

2025-2026 Newly Approved Medications

Infectious Diseases

- Zoliflodacin
- Doravirine & Islatravir



Zoliflodacin – Nuzolvence®

Indication

- To treat uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae in adults and pediatric patients ≥ 12 years old and ≥ 35 kg

Mechanism of Action

- Spiropyrimidinetrione inhibitor of the bacterial type II topoisomerases required for DNA synthesis. Binds within the cleaved DNA-gyrase complex, thereby blocking re-ligation.

Dosing & Administration

- 3g (one packet) orally as a single dose
  - 35 to < 50 kg: give on an empty stomach, 1 hour before or 2 hours after food
  - ≥ 50 kg: give with food
- Must be mixed with water prior to administration
- Should administer full dose within 15 minutes of mixing

Approval Date: 12/12/2025

Nuzolvence. Prescribing Information. Waltham, MA: La Jolla Pharmaceutical Company; December 2025.

Zoliflodacin – Nuzolvence®

Contraindications

- Known history of hypersensitivity
- Concomitant use with moderate or strong CYP3A4 inducers

Precautions

- Embryo-Fetal toxicity—avoid use during pregnancy, males with female partners should use effective contraception for at least 3 months
- Testicular toxicity and risks to male fertility
- Hypersensitivity reactions, including rash and pruritus
- *Clostridioides difficile* infection

Adverse Reactions

- Neutropenia (12%), headache (10%), leukopenia (9%), dizziness (3%), nausea (3%), diarrhea (2%)

Nuzolvence. Prescribing Information. Waltham, MA: La Jolla Pharmaceutical Company; December 2025.

Doravirine & Islatravir – Idvynso™

[1]RT=reverse transcriptase

Indication

- To treat HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically-suppressed on a stable antiretroviral regimen

Mechanism of Action

- Doravirine: non-nucleoside reverse transcriptase inhibitor; inhibits replication via inhibition of RT[1].
- Islatravir: deoxyadenosine nucleoside analog RT[1] inhibitor; phosphorylated to active form which inhibits RT[1] following incorporation into viral DNA.

Dosing & Administration

- One tablet orally twice daily (fixed dose combination of the antiretroviral drugs doravirine and islatravir)
- Take with or without food
- Dose adjust with rifabutin: take one combination tablet once daily, then one tablet of doravirine 100 mg ~12 hours later

Approval Date: 4/20/2026

Idvynso. Prescribing Information. Rahway, NJ: Merck & Co., Inc.; April 2026.

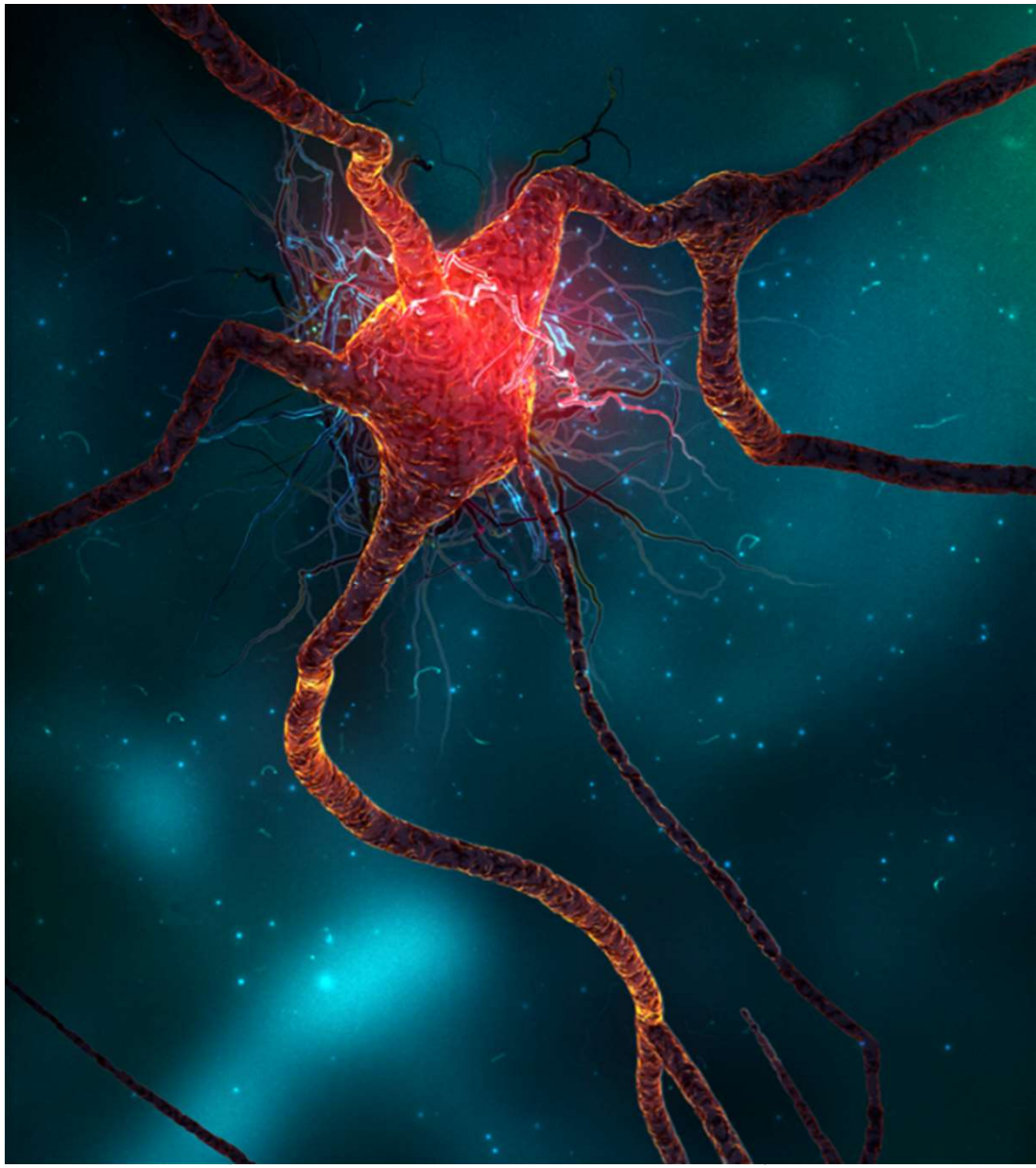
Doravirine & Islatravir – Idvynso™

Contraindications	• Concomitant use of strong CYP3A4inducers (decreased doravirine concentrations) • Co-administration with lamivudine or emtricitabine (deoxycytidine kinase substrates which may decrease active islatravir concentrations)
Precautions	• Severe skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)
Adverse Reactions	• Diarrhea (3%), dizziness (2%), fatigue (2%), abdominal distension (2%), headache (2%), increased weight (2%)
Special Considerations	• Considered a complete regimen, co-administration with other antiretrovirals is not recommended

Idvynso. Prescribing Information. Rahway, NJ: Merck & Co., Inc.; April 2026.

Neurology/ Psychiatry

- Milsaperidone
- Tradipitant



Milsaperidone – Bysanti™

Indication

- To treat schizophrenia and to treat manic or mixed episodes associated with bipolar I disorder

Mechanism of Action

- Suspected that effect is mediated through a combination of dopamine (D_2) and serotonin (5-HT_2) antagonism

Dosing & Administration

- Orally twice daily with or without food
- Titrate to reduce risk of orthostatic hypotension; after titration, recommended maintenance doses for: 1) Schizophrenia: 6-12 mg twice daily and 2) Bipolar mania: 12 mg twice daily
- See label for details about dosing for: 1) poor CYP2D6 metabolizers, 2) hepatic impairment, 3) drug interactions
- Drug interactions: 1) Strong CYP2D6 and/or strong CYP3A4 inhibitors and 2) Drugs that lower blood pressure

Approval Date: 2/20/2026

Bysanti. Prescribing Information. Washington, D.C.: Vanda Pharmaceuticals Inc.; February 2026.

Milsaperidone – Bysanti™

Contraindications

- Known history of hypersensitivity

Precautions

- Cerebrovascular adverse reactions in elderly patients with dementia
- QTc prolongation
- Neuroleptic malignant syndrome (NMS)
- Orthostatic hypotension and syncope
- Leukopenia, neutropenia, and agranulocytosis
- Priapism
- Potential for cognitive and motor impairment

Adverse Reactions

- ≥ 5% and 2-fold greater than placebo: dizziness, dry mouth, tachycardia, fatigue, nasal congestion, orthostatic hypotension, somnolence, weight increased, hepatic enzymes increased

Bysanti. Prescribing Information. Washington, D.C.: Vanda Pharmaceuticals Inc.; February 2026.

Tradipitant – Nereus™

Indication	• To treat vomiting associated with motion
Mechanism of Action	• Selective, high-affinity antagonist of human substance P/neurokinin-1 (NK-1) receptors in the central nervous system; exact mechanism by which treats vomiting is not fully established
Dosing & Administration	• 85 mg or 170 mg as a single oral dose approximately 60 minutes prior to event expected to cause vomiting induced by motion • Administer on empty stomach, at least 1 hour before or 2 hours after a meal • Should not exceed a single dose of 85 mg or 170 mg in 24 hours • Safety beyond 90 doses has not been established

Approval Date: 12/30/2025

Nereus. Prescribing Information. Washington, D.C.: Vanda Pharmaceuticals Inc.; December 2025.

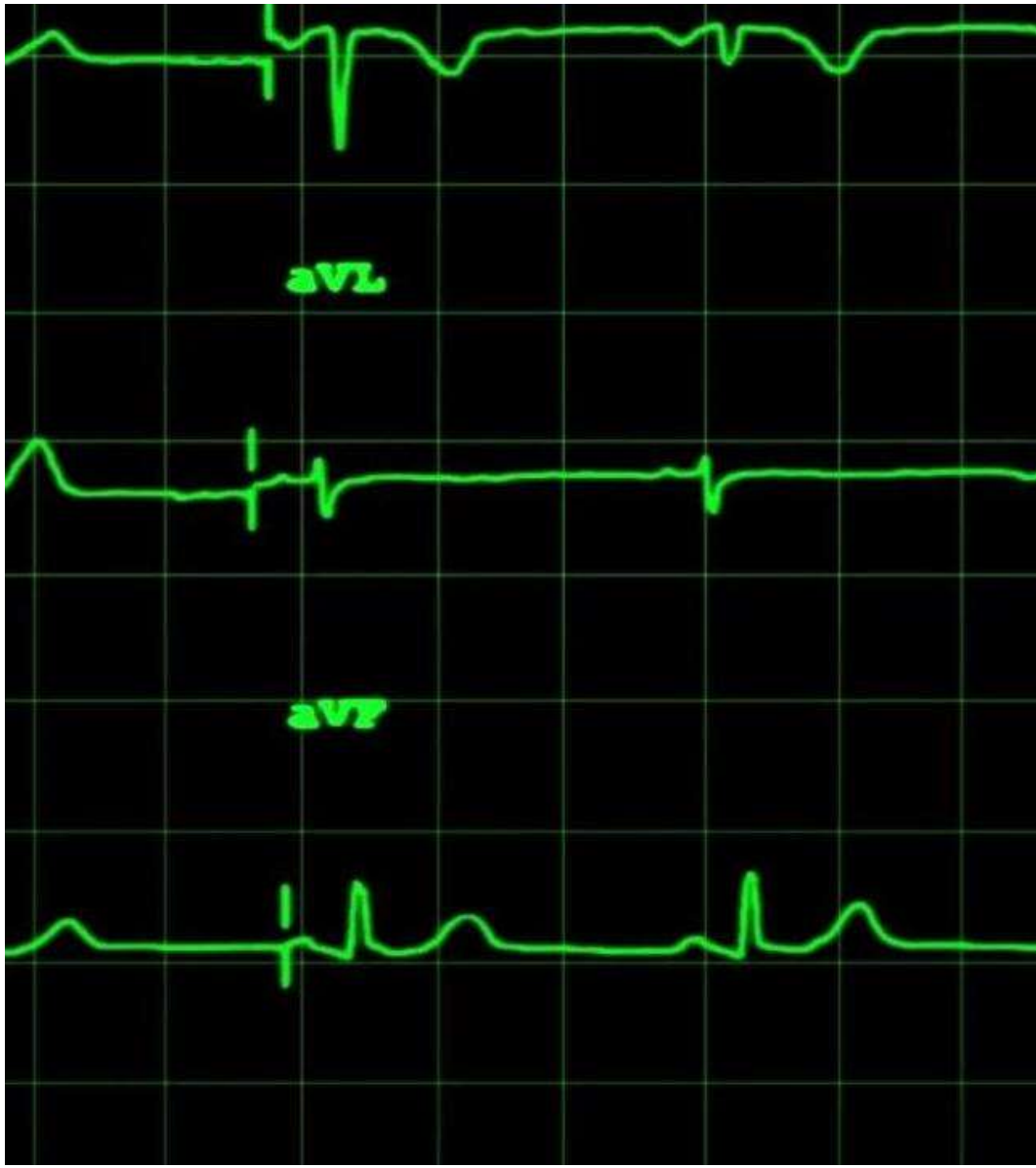
Tradipitant – Nereus™

Contraindications	• None
Precautions	• Effects on ability to drive or operate machinery
Adverse Reactions	• Somnolence (6% with 85 mg dose, 12% with170 mg dose), headache (7% with 85 mg dose, 10% with170 mg dose), fatigue (6% with 85 mg dose, 8% with170 mg dose)
Special Considerations	• Strong CYP3A4 inhibitors may increase tradipitant exposure and risk of adverse reactions • Monitor breastfed infants for somnolence

Nereus. Prescribing Information. Washington, D.C.: Vanda Pharmaceuticals Inc.; December 2025.

Cardiovascular/ Renal

- Baxdrostat
- Etripamil
- Lerodalcibep-liga



Baxdrostat – Baxfendy™

Indication	• Hypertension in combination with other antihypertensive drugs to lower blood pressure in adults who are not adequately controlled on other agents
Mechanism of Action	• Inhibits aldosterone synthase, thereby reducing aldosterone concentrations and thus reducing sodium and water retention by the kidneys
Dosing & Administration	• Monitor potassium and sodium prior to initiation • 2 mg orally once daily with or without food • Reduce dose to 1 mg daily if increased risk of hyperkalemia or hyponatremia

Approval Date: 5/15/2026

Baxfendy. Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.

Baxdrostat – Baxfendy™

Contraindications	• None
Precautions	• Hyperkalemia and hyponatremia • Assess prior to initiation and periodically during treatment
Adverse Reactions	• ≥ 2% and greater (≥ 1%) than placebo: hyperkalemia (most common), hypotension, hyponatremia, dizziness, muscle spasms
Special Considerations	• Monitor more frequently if given concomitantly with other drugs that increase serum potassium • Concomitant use of strong and moderate CYP3A inducers may decrease concentrations of baxdrostat (a CYP3A substrate)

Baxfendy. Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.

Etripamil – Cardamyst™

Indication	• To treat episodes of paroxysmal supraventricular tachycardia (PSVT)
Mechanism of Action	• L-type calcium influx inhibitor that modulates influx of ionic calcium across the cell membrane of AV nodal cells, thereby interrupting reentry and restoring sinus rhythm
Dosing & Administration	• Administered intranasally • Initial Dose: 70 mg administered as two nasal sprays, one spray into each nostril • Repeat Dose (if needed): If symptoms persist 10 minutes, administer a second 70 mg dose • Do not exceed 140 mg in 24 hours • Each device delivers two sprays for a total dose of 70 mg etripamil

Approval Date: 12/12/2025

Cardamyst. Prescribing Information. Charlotte, NC: Milestone Pharmaceuticals USA, Inc.; December 2025.

Etripamil – Cardamyst™

Contraindications	• History of hypersensitivity • Heart failure – New York Heart Association (NYHA) Class II to IV • Wolff-Parkinson-White (WPW), Lown-Ganong-Levine (LGL) syndromes, or manifest pre-excitation (delta wave) on ECG • Sick sinus syndrome (unless permanent pacemaker) or second degree atrioventricular (AV) Mobitz 2 block or higher
Precautions	• Syncope (recommended to administer in sitting position)
Adverse Reactions	• Nasal discomfort (23-28%), nasal congestion (12-14%), rhinorrhea (10-12%), throat irritation (6-7%), epistaxis (6-7%)
Special Considerations	• Lactating women should pump and discard breastmilk for 12 hours after administration

Cardamyst. Prescribing Information. Charlotte, NC: Milestone Pharmaceuticals USA, Inc.; December 2025.

Lerodalcibep-liga – Lerochol®

[1]LDL-C=low-density lipoprotein cholesterol
[2]PCSK9=proprotein convertase subtilisin/kexin type 9
[3]LDLR=low-density lipoprotein receptor

Indication	• To reduce LDL-C[1] in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia, as an adjunct to diet and exercise
Mechanism of Action	• Recombinant fusion protein that binds PCSK9[2] and inhibits binding to LDLR[3] on surface of hepatocytes which increases number of LDLRs available to clear LDL-C from the blood
Dosing & Administration	• 300 mg subcutaneously once monthly • Available as 300 mg/1.2 mL solution in a single-dose prefilled syringe • Inject subcutaneously into abdomen or in thigh; caregiver or healthcare professional may administer in upper arm

Approval Date: 12/12/2025

Lerochol. Prescribing Information. Cincinnati, OH: LIB Therapeutics, Inc.; December 2025.

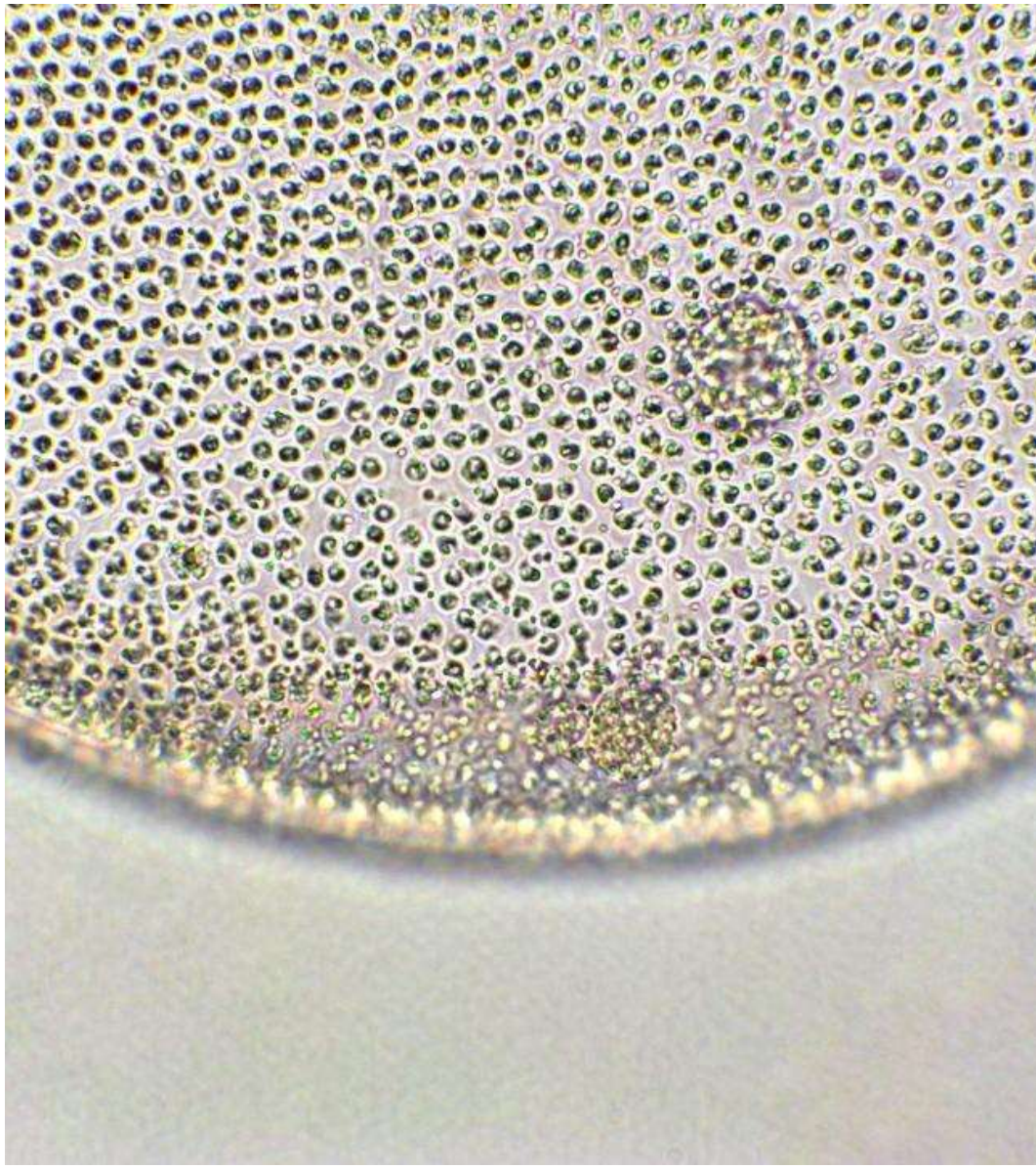
Lerodalcibep-liga – Lerochol®

Contraindications	• None
Precautions	• None
Adverse Reactions	• Injection site reactions (12-18%), nasopharyngitis (13-15%), diarrhea (3%), peripheral edema (2%), nausea (2%)
Special Considerations	• Recommended to be stored in the refrigerator, in the original carton, and protected from light • If necessary, may store at room temperature for up to 3 months

Lerochol. Prescribing Information. Cincinnati, OH: LIB Therapeutics, Inc.; December 2025.

Endocrine

- Orforglipron
- Insulin icodec-abae
- Elinzanetant



Orforglipron – Foundayo™

Indication

- To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition, in combination with a reduced-calorie diet and increased physical activity

Mechanism of Action

- GLP-1 receptor agonist that regulates appetite and caloric intake

Dosing & Administration

- Starting dose is 0.8 mg orally once daily with or without food
- Increase dose after at least 30 days to 2.5 mg daily then continue to increase every 30 days based on treatment response from 5.5 mg, then 9 mg, then 14.5 mg, then 17.2 mg (max dose)
- Not recommended in severe hepatic impairment

Approval Date: 4/1/2026

Foundayo. Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2026.

Orforglipron – Foundayo™

[1]MTC=medullary thyroid carcinoma
[2]MEN 2 =multiple endocrine neoplasia syndrome type 2

Contraindications

- Personal or family history of MTC[1] or in patients with MEN 2[2]
- History of hypersensitivity

Precautions

- **Boxed warning:** thyroid c-cell tumors
- Acute pancreatitis
- Severe gastrointestinal reactions
- Acute kidney injury due to volume depletion
- Hypoglycemia (especially with concomitant insulin or an insulin secretagogue)
- Hypersensitivity reactions
- Diabetic retinopathy complications in patients with type 2 diabetes
- Acute gallbladder disease
- Pulmonary aspiration during general anesthesia

Foundayo. Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2026.

Orforglipron – Foundayo™

Adverse Reactions

- ≥ 5% and greater (≥ 2%) than placebo: nausea (most common), constipation, diarrhea, vomiting, dyspepsia, abdominal pain, headache, abdominal distension, fatigue, eructation, gastrointestinal reflux disease, flatulence

Special Considerations

- May cause fetal harm, recommended to discontinue when pregnancy is recognized
- Advise females using oral contraceptives to switch to a non-oral contraceptive method or add a barrier method for 30 days after initiation and 30 days after each dose escalation

Foundayo. Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2026.

Insulin icodec-abae – Awiqli®

Indication

- To improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise

Mechanism of Action

- Insulin/insulin analogs lower blood glucose by stimulating peripheral glucose uptake and inhibiting hepatic glucose production
- Binds to albumin, resulting in a depot in circulation from which it is slowly released causing stable glucose-lowering over the dosing interval (1 week)

Dosing & Administration

- Individualize dosing based on patient specific factors
- Inject into thigh, upper arm or abdomen; rotate sites
- Prescribing information has more information on initiating dosing and switching from daily basal insulin therapy

Approval Date: 3/26/2026

Awiqli. Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; March 2026.

Insulin icodec-abae – Awiqli®

Contraindications

- During episodes of hypoglycemia
- History of hypersensitivity

Precautions

- Hypoglycemia including life-threatening hypoglycemia; hyper-/hypoglycemia with changes in regimen or medication errors
- Hypokalemia
- Fluid retention and heart failure with concomitant use of thiazolidinediones

Adverse Reactions

- Hypoglycemia, hypersensitivity reactions (e.g., urticaria, swelling face and lips), injection site reactions, lipodystrophy, pruritus, rash, edema, weight gain

Awiqli. Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; March 2026.

Insulin icodec-abae – Awiqli®

Special Considerations

- Drug interactions may increase risk of hypoglycemia or may decrease blood glucose lowering effect (see prescribing information)
- Drug interactions may blunt symptoms of hypoglycemia (e.g. beta-blockers, clonidine)
- Available as clear/colorless solution: 700 units/mL (U-700)
  - 3 mL single-patient-use FlexTouch® prefilled pen (containing 2,100 units)
  - 1.5 mL single-patient-use FlexTouch® prefilled pen (containing 1,050 units)
  - 1 mL single-patient-use FlexTouch® prefilled pen (containing 700 units)

Awiqli. Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; March 2026.

Elinzanetant – Lynkuet®

Indication

- To treat moderate-to-severe vasomotor symptoms due to menopause

Mechanism of Action

- Dual neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist which modulates neuronal activity in thermoregulation associated with hot flashes

Dosing & Administration

- 120 mg orally once daily at bedtime with or without food
- Capsules should be swallowed whole, not cut, crushed, or chewed
- Baseline LFTs before initiating and throughout treatment
- Drug Interactions:
  - Concomitant moderate CYP3A4 inhibitors: Reduce dose to 60 mg once daily
  - Concomitant strong CYP3A4 inhibitors, grapefruit (juice), or strong/moderate CYP3A4 inducers: Avoid use

Approval Date: 10/24/2025

Lynkuet. Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2025.

Elinzanetant – Lynkuet®

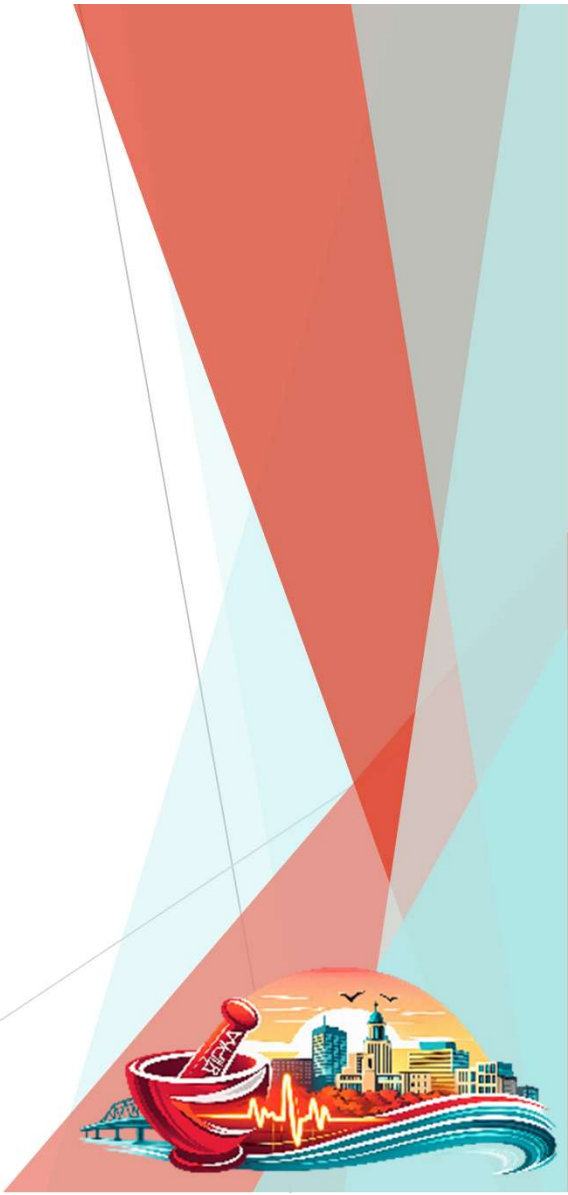
Contraindications	• Pregnancy
Precautions	• CNS depressant effect and daytime impairment • Hepatic transaminase elevations • Risk of pregnancy loss • Risk of seizures in patients with a history of seizures
Adverse Reactions	• ≥ 2% and greater than placebo: headache, fatigue, gastroesophageal reflux disease, dizziness, nausea, and somnolence
Special Considerations	• Use in patients with end stage renal disease with or without hemodialysis orin patients with moderate to severe hepatic impairment is not recommended

Lynkuet. Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2025.

Medication Updates

Generic Options

Market Withdrawals



Recent Generics

Flovent HFA® (fluticasone propionate)	Atrovent HFA® (ipratropium)
Xarelto® (rivaroxaban)	Janumet XR® (sitagliptin/metformin ER)
Jentadueto® (linagliptin/Metformin)	Nucynta® ER (tapentadol ER)
Tradjenta® (linagliptin)	Pentasa® (mesalamine)
Farxiga® (dapagliflozin)	

U.S Food and Drug Administration, 2025.
https://pharmacist.therapeuticresearch.com

Upcoming Generics

Fanapt® (Iloperidone)	Savaysa® (Edoxaban)
Eliquis® (Apixaban)	Invokana® (Canagliflozin)
	Brilinta® (Ticagrelor)

U.S Food and Drug Administration, 2025.
https://pharmacist.therapeuticresearch.com

Drugs Withdrawn/Recalled from the Market

Generic Name	Recall or Withdrawal	Reason / Issue
Duloxetine delayed-release capsules	Recall	Elevated nitrosamine impurities → may increase cancer risk
Chlorthalidone	Recall	Failed dissolution → affecting absorption and effectiveness
Amlodipine/Olmesartan medoxomil	Recall	Certain lots contained substandard amounts of Olmesartan → potency concerns
Epinephrine Injection USP	Recall	Potential impurities and stability concerns
Doxorubicin Hydrochloride Liposome Injection	Recall	Presence of glass particles in affected lots
Magnesium Sulfate in Water for Injection	Recall	Labeling error/misidentification → medication errors
Lactated Ringer's Injection	Recall	Impurities detected
Coal tar eczema treatment cream	Recall	Microbial contamination with Staphylococcus aureus

U.S Food and Drug Administration, 2025.
https://pharmacist.therapeuticresearch.com

Drugs Withdrawn /Recalled from the Market

Generic Name	Recall or Withdrawal	Reason / Issue
Avacopan	FDA-requested market withdrawal (under review)	Concerns regarding clinical efficacy and reports of serious liver injury. Product remained available as of June 2026 pending further review.
Leucovorin calcium	Market withdrawal	Withdrawn at the manufacturer's request because the product was no longer marketed; not related to safety or efficacy concerns.
Obeticholic acid	Market withdrawal	Postmarketing data showing increased risk of serious liver injury, liver transplants, and death.

U.S Food and Drug Administration, 2025.
https://pharmacist.therapeuticresearch.com

Questions???

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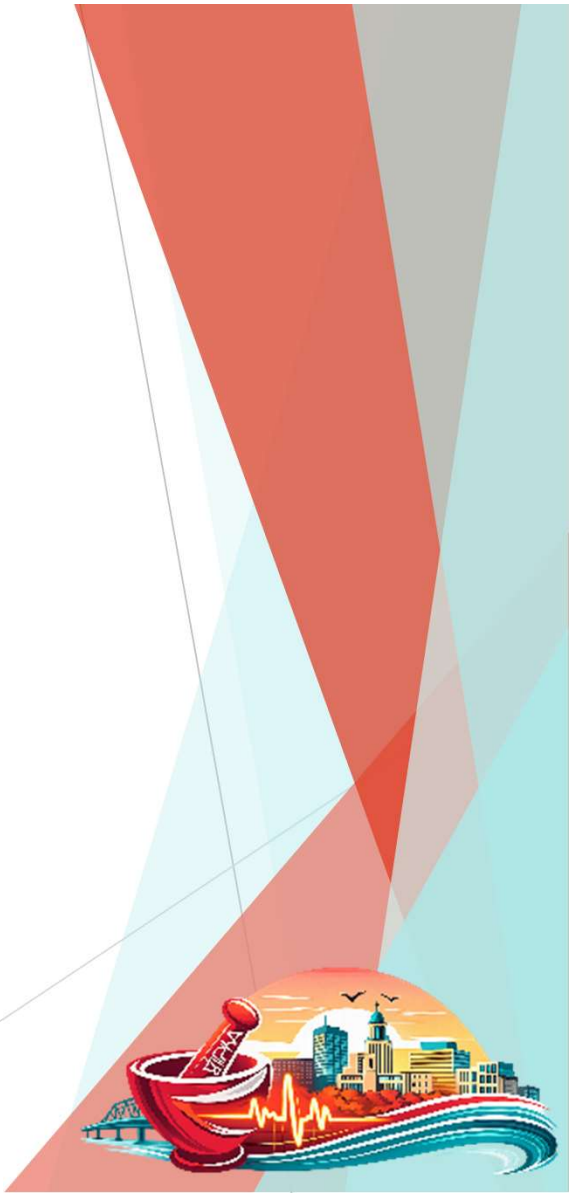
Post-Test Question #1



Which newly approved medication requires monitoring of liver function tests before initiation and during therapy?

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Which newly approved medication is FDA approved to treat vomiting associated with motion?

A. Milsaperidone
B. Zoliflodacin
C. Tradipitant
D. Doravirine/Islatravir

Post-Test Question #3

Which medication recently became available as a generic in the United States?

A. Apixaban
B. Edoxaban
C. Canagliflozin
D. Tapentadol ER

Post-Test Question #4

Final tips & Take Home Points

- There were 46 NME approved in 2025, there have been 29 NME approved in 2026
- New medications are constantly being reviewed and approved by the FDA
- This changes the treatment options for patients and prescribers
- As providers we must be vigilant to keep up with these new medications and at the very least know where to quickly find information related to new medications

Resources and References

FDA New Drug Innovation webpage

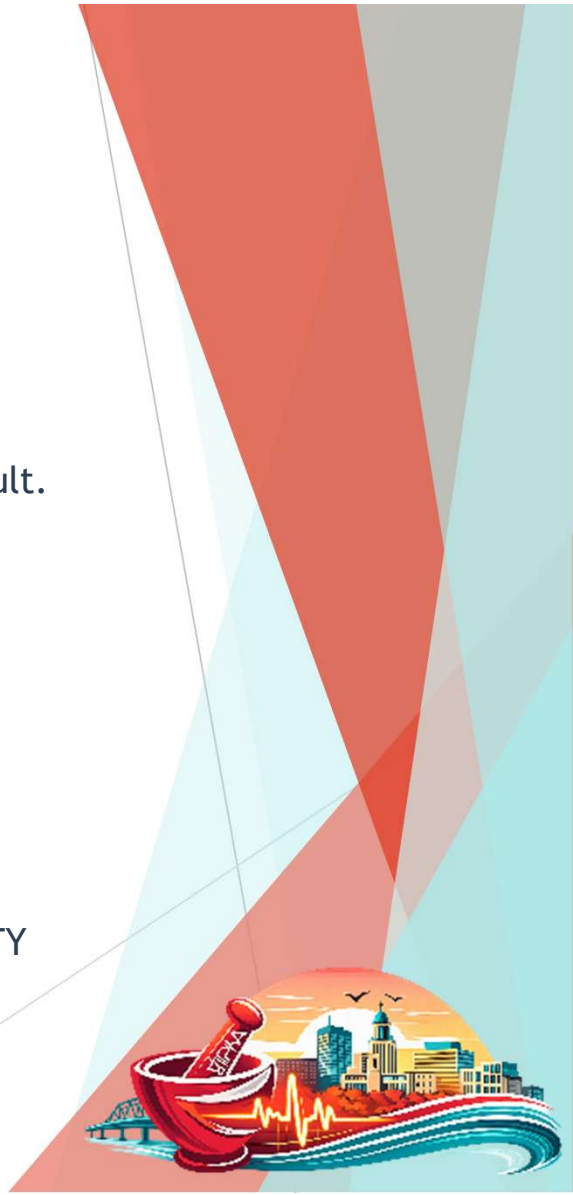
- https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm

CenterWatch webpage for newly approved medications

- http://www.centerwatch.com/drug-information/fda-approved-drugs/

Pharmacist Letter webpage for newly approved medications

- http://pharmacistsletter.therapeuticresearch.com/pl/NewDrugs.aspx?cs=FACULTY&s=PL



Resources and References

- Awiqli. Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; March 2026.
- Baxfendy. Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.
- Bysanti. Prescribing Information. Washington, D.C.: Vanda Pharmaceuticals Inc.; February 2026.
- Cardamyst. Prescribing Information. Charlotte, NC: Milestone Pharmaceuticals USA, Inc.; December 2025.
- Foundayo. Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2026.
- Idvynso. Prescribing Information. Rahway, NJ: Merck & Co., Inc.; April 2026.
- Lynkuet. Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2025.
- Lerochol. Prescribing Information. Cincinnati, OH: LIB Therapeutics, Inc.; December 2025.
- Nereus. Prescribing Information. Washington, D.C.: Vanda Pharmaceuticals Inc.; December 2025.
- Nuzolvence. Prescribing Information. Waltham, MA: La Jolla Pharmaceutical Company; December 2025.

Thank you

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