# KPhA New Drugs 2026

University of Kansas Student Pharmacists

Amanda Applegate, PharmD, BCACP

*KPhA works with the Kentucky Pharmacy Education and Research Foundation, Inc. to certify its courses. KPERF is accredited by ACPE as a provider of continuing pharmacy education.*

ACPE UAN 0143-9999-26-075-L01-P/T



# DISCLOSURES

**Faculty**

Amanda Applegate, faculty for this activity, has been a Quality Improvement committee member with Sunflower Health Plan since 2025.

**Planners**

None of the planners for this activity have any relevant financial relationships with ineligible companies to disclose.



# THANK YOU REVIEWERS!

| Pharmacist Reviewer | Student Pharmacist |
|---|---|
| Erica Wilkinson | Penner Fox |
| Logan Kiser | Leyton Brown |
| Maddy Livengood | Hannah Lewis |
| Carleigh Kruger | Paige Holopirek |
| Emily Prohaska | Emily Woods |
| Megan Martin | Emily Scott |
| Robert O'Neill | Makenzie Flax |





# OBJECTIVES - PHARMACISTS

1. Identify therapeutic indications for each of the new drugs.
2. Identify mechanisms of action and key adverse events of the new drugs.
3. State the route of administration for each new drug and key considerations regarding dosage and administration.
4. Compare new therapeutic agents with older medications to which they are most similar in properties and/or use and identify the most important advantages and disadvantages of the new drugs.

## OBJECTIVES - TECHNICIANS

1. Identify therapeutic indications for each of the new drugs.
2. Identify mechanisms of action and key adverse events of the new drugs.
3. State the route of administration for each new drug and key considerations regarding dosage and administration.





## PRE-TEST

1. What is the mechanism of action of Blujepa?
2. What is the approved indication for Bysanti?
3. Lynkeut is contraindicated in those with severe renal impairment (T/F)
4. Which is true regarding the administration of Nereus?



# Lynkuet (elinzanetant)

Penner (Fox) Cason

## OBJECTIVES

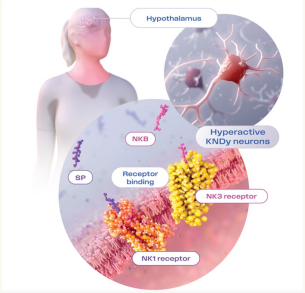
1. Identify indications of Lynkuet
2. Identify mechanisms of action and key adverse events of Lynkuet
3. State the route of administration and key considerations regarding dosage and administration of Lynkuet
4. Compare with older medications to which Lynkuet is most similar in properties
5. Identify the most important advantages and disadvantages of Lynkuet

# INDICATIONS

Lynkuet is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

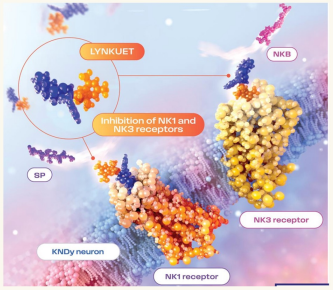
# MECHANISM OF ACTION

- In the hypothalamus, there are kisspeptin/neurokinin B/dynorphin (KNDy) neurons that have neurokinin 1 (NK1) and neurokinin 3 (NK3) receptors.
- Substance P (SP) works on NK1 receptors and Neurokinin B (NKB) works on NK3 receptors to help regulate body temperature.
- During menopause, KNDy neurons become hyperactive and there are increased levels of SP and NKB. This can lead to hot flashes.




# MECHANISM OF ACTION

- LYNKUET is a NK1 and NK3 receptor antagonist.
- Antagonism of NK1 and NK3 on KNDy nerons leads to inhibition of Substance P and Neurokinin B.
- This can modulate neuronal activity in thermoregulation associated with hot flashes.




# ROUTE OF ADMINISTRATION AND CONSIDERATIONS

- 120 mg PO once daily at bedtime
- Take with water; do not cut, crush, or chew
- No effect w/ or w/o food

**Table 1. Dosage Modifications for Drug Interactions**

| Concomitant Drug | LYNKUET Dosage |
|---|---|
| Strong CYP3A4 inhibitors and grapefruit (juice) | Avoid concomitant use |
| Moderate CYP3A4 inhibitors | 60 mg (one capsule) orally once daily at bedtime *[see Storage and Handling (16.2)]*.<br>After discontinuation of the moderate CYP3A4 inhibitor (after 3 to 5 half-lives of the inhibitor), LYNKUET should be used at the usual dosage of 120 mg once daily. |
| Strong and Moderate CYP3A4 inducers | Avoid concomitant use |

# ADVERSE EFFECTS

- Headache (9.6%)
- Fatigue (7.3%)
- Dizziness (6.1%)
- Somnolence (5.1%)
- Abdominal Pain (4.5%)
- Rash (4.2%)
- Diarrhea (3.8%)
- Muscle Spasms (3.2%)

# CONTRA-INDICATIONS

- Pregnancy

# WARNINGS & PRECAUTIONS

- CNS Depressant Effect and Daytime Impairment
- Hepatic Transaminase Elevations
  - baseline and 3 mo follow-up labs
  - d/c if transaminanse >5x ULN
  - d/c if transaminase >3x ULN and total bilirubin >2x ULN
- Risk of seizures in history of seizures
- Risk of pregnancy loss

Specific Populations:

- End Stage Renal Disease with or without hemodialysis: Not studied, so not recommended
- Moderate to Severe Hepatic Impairment: Not studied, so not recommended

| | Lynkuet (elinzanetant) | Veozah (fezolinetant) |
|---|---|---|
| MOA | NK1 and NK3 receptor antagonist | selective NK3 receptor antagonist |
| Most Common AEs | headache, fatigue, dizziness and somnolence | abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation. |
| Contraindications | Pregnancy | Known cirrhosis; severe renal impairment or end-stage renal disease; concomitant use with CYP1A2 inhibitors |
| Major CYP Interactions | CYP3A4 Inhibitors and Inducers | CYP1A2 Inhibitors |
| Monitoring | LFTS at baseline and month 3 | LFTs at baseline, monthly for first 3 months, then month 6 and 9 |
| Liver Impairment | May cause elevated liver transaminases | May cause elevated liver transaminases; BW: hepatotoxicity |

# ADVANTAGES & DISADVANTAGES

Non-hormonal treatment is a great option for women with history of breast cancer or blood clots

Has less liver toxicity and fewer contraindications than Veozah

More CNS effects than Veozah

*any*
# QUESTIONS?

pennerfox@ku.edu

## REFERENCES & RESOURCES

UpToDate Lexidrug: Elinzanetant

Lynkuet-us.com

Veozah.com

# CARDAMYST (etripamil)

Leyton Brown
Fourth Year Student Pharmacist
KU School of Pharmacy

## Use of Etripamil

**Indication:**

- Conversion of acute symptomatic episodes of PSVT in adults to normal sinus rhythm

## Mechanism of Action

1. **L-Type Calcium Influx Inhibitor**

**2. Modulates Calcium Influx across cell membrane of AV node, along with arterial smooth muscles and contractile myocardial cells**

**3. Interruption of AV node reentry restores normal sinus rhythm**

## Side Effects

**Due to effects on BP, HR, and cardiac conduction Etripamil may cause dizziness and syncope in patients**

**Other:**

| | Placebo N=223 % | CARDAMYST 70 mg N=235 % | CARDAMYST 2x70 mg[2] N=86 % |
|---|---|---|---|
| Nasal Discomfort | 6 | 28 | 23 |
| Nasal Congestion | 1 | 14 | 12 |
| Rhinorrhea | 2 | 12 | 10 |
| Throat Irritation | 1 | 7 | 6 |
| Epistaxis | 1 | 6 | 7 |

1) Adverse reactions that occurred within 24 hours of study drug administration (TEAE24h) for perceived PSVT in the double-blind, placebo-controlled studies, NODE-1, NODE-301 Part 1, RAPID and RAPID Extension that had an overall incidence of 5% or greater and where the incidence is at least 1% greater than the placebo group.

2) 2x70 mg: first administration of etripamil 70 mg followed by a second dose of etripamil 70 mg 10 minutes later if symptoms persisted.

## Dosing

**1 spray into each nostril for an initial dose of 70mg**

**If symptoms persist use a second device and give another spray into each nostril (70mg total)**

**MAX of 140mg in 24 hour period**

## Administration

**Intranasal:**

- Administer as soon as possible after symptom onset, 2 devices per package, each device delivers 2 sprays, if repeat administration necessary a new device must be used.

**Instructions for use:**

- **DO NOT PRIME OR TEST DEVICE PRIOR TO ADMINISTRATION**
- While sitting, insert device into nostril keeping head straight, and spray 1 spray in each nostril by pressing plunger firmly and quickly, breathe normally **(DO NOT INHALE DEEPLY)**, remain seated and keep head straight for 10 mins
- Wait 10 mins before re-administering if full dose wasnt given the first time
- Wipe away any medicine that drips from nose but **DO NOT** blow nose for 10 minutes
- If symptoms do not improve after 2 doses seek medical attention.

## How does Etripamil compare to other agents?

**Etripamil VS Adenosine:**

**Advantages:**
- Self administration
- May avoid costs of ER visit
- Fewer systemic side effects

**Disadvantages:**
- Requires medical triage
- Lower Efficacy Rate (RAPID trial shows it terminates PSVT in about 64% of patients in 30 minutes)

**Etripamil VS "pill in pocket" (flecainide/propafenone):**

**Advantages:**
- Rapid onset (in trials successfully converted to normal sinus rhythm in a median time of 17 mins)
- Higher efficacy (64% in clinical trials vs about a 50% efficacy rate for pill in pocket approach)

**Disadvantages:**
- Higher cost

## Cost

- Average Retail price without insurance ranges from $1600-$2000 for standard package
- Commercially insured patients can get a copayment card from the manufacturer which can lower the cost to as low as $25

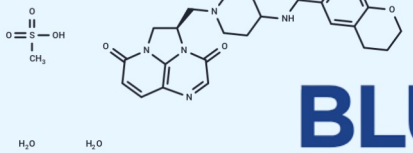

## References


- "CARDAMYST" (etripamil) Nasal Spray: Full Prescribing Information. Milestone Pharmaceuticals, 2025. Accessed 26 May 2026. https://milestonepharma.com/etripamilprescribinginformation.pdf
- "Etripamil" *Lexi-Comp Online,* Wolters Kluwer Clinical Drug Information, Accessed 26 May 2026. https://online-lexi-com.www2.lib.ku.edu/lco/action/doc/retrieve/docid/patch_f/7663092?cesid=515B3fxu4H7&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dcardamyst%26t%3Dname%26acs%3Dtrue%26acq%3DCardamyst
- Jha, M., Song, D., Kung, A., Lo, S., Sacher, A., Ang, S. P., Akthar, A., Jain, H., Ahmed, R., Bates, M., Lee, S., & Goldbarg, S. (2025, May 26). *Efficacy and safety of intranasal etripamil for paroxysmal supraventricular tachycardia: Meta-analysis of randomized controlled trials*. Journal of clinical medicine. https://pmc.ncbi.nlm.nih.gov/articles/PMC12155871/


## Thank You!

Any Questions?

- Email: Leytonb16@ku.edu



# BLUJEPA

## (gepotidacin) 750 mg tablets

Developed by GSK

**HANNAH CAMILLE LEWIS**
University of Kansas - School of Pharmacy
PharmD Candidate 2028

## INDICATIONS & THERAPEUTIC USES:

**CYSTITIS, ACUTE UNCOMPLICATED OR ACUTE SIMPLE CYSTITIS**
FEMALES ≥12 YEARS OF AGE WEIGHING ≥ 40 KG.

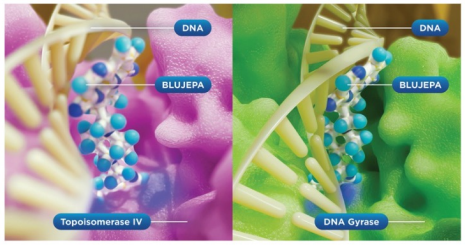
Treatment of uncomplicated urinary tract infection (uUTI) caused by susceptible Escherichia coli (E.coli), Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, and Enterococcus faecalis.

**GONOCOCCAL INFECTION, UNCOMPLICATED:**
PATIENTS ≥ 12 YEARS OF AGE WEIGHING ≥ 45 KG WITH LIMITED OR NO ALTERNATIVE TREATMENT OPTIONS.

Treatment of uncomplicated urogenital gonorrhea caused by susceptible Neisseria gonorrhoeae.

## MECHANISM OF ACTION

Triazaacenaphthylene antibacterial that inhibits type II topoisomerases, including bacterial topoisomerase II (DNA gyrase) and topoisomerase IV, resulting in inhibition of DNA replication.




## DOSAGE FORMS / HOW SUPPLIED

| | | |
|---|---|---|
| **ORAL TABLET** | **YELLOW, OBLONG** | **IMPRINTED: "GS GU3"** |
| **750 MG** | **FILM-COATED** | **MESYLATE SALT** |

Bottle of 8 tablets (NDC 0173-0922-38)
Bottle of 20 tablets (NDC 0173-0922-45)

*There are currently no generic products available.*

## DOSAGE AND ROUTE OF ADMINISTRATION

| CYSTITIS, ACUTE UNCOMPLICATED OR ACUTE SIMPLE | GONOCOCCAL INFECTION, UNCOMPLICATED |
|---|---|
| Oral: 1,500 mg (2 tablets) every 12 hours for 5 days. | Oral: 3,000 mg (4 tablets) as a single dose, followed by a second 3,000 mg dose ~12 hours later. |
| Note: Reserve use for infection caused by drug-resistant pathogens with limited treatment options | Note: Due to the risk of QTc interval prolongation, do not increase the dose, extend the duration of treatment, or reduce the interval between doses. |

*Administer BLUJEPA tablets after a meal to reduce the possibility of gastrointestinal intolerance.*

## DOSAGE CONSIDERATIONS

| | |
|---|---|
| **ALTERED KIDNEY FUNCTION** | eGFR <30 mL/minute: Avoid use |
| **ALTERED LIVER FUNCTION** | Severe impairment: Avoid use |

**Children < 12 years**: safety and effectiveness has not been established.

**Pregnancy**: there is no available data on the use of BLUJEPA in pregnant women.

**Breastfeeding**: there is currently no data on the presence of geoptidacin in human milk, its effects on breastfed children, or on milk production.

## WARNINGS AND PRECAUTIONS

| QTC PROLONGATION | ACETYLCHOLINESTERASE INHIBITION | CLOSTRIDIOIDES DIFFICILE-ASSOCIATED DIARRHEA |
|---|---|---|
| A dose and concentration-dependent prolongation of the QTc interval has been observed in patients being treated with BLUJEPA. | BLUJEPA is an acetylcholinesterase inhibitor, which can lead to increased cholinergic effects:<br>◦ Atrioventricular block<br>◦ Bradycardia<br>◦ Bronchospasm<br>◦ Seizures/convulsions<br>◦ Vasovagal Syncope | Clostridioides difficile infection (CDI) has been reported with nearly all systemic antibacterial agents, including BLUJEPA. |

*BLUJEPA is <u>contraindicated</u> in patients with a history of severe hypersensitivity to gepotidacin or any other component of the formula.*

*There are currently <u>NO</u> black box warnings for BLUEJEPA.*

## COMMON ADVERSE EFFECTS:

**> 10%**

GI:
- Diarrhea (16%)

**1% - 10%**

GI:
- Abdominal Pain (4%)
- Flatulence (3%)
- Nausea (9%)
- Vomiting (2%)

GENITOURINARY:
- Vulvovaginal Candidiasis (1%)

NERVOUS SYSTEM:
- Dizziness (2%)
- Headache (2%)

**< 1%**

CV:
- Presynocope
- Tachycardia

OPTHALMIC:
- Blurred Vision

DERMATOLOGIC:
- Hyperhidrosis
- Skin rash

NEUROMUSCULAR:
- Muscle Spasm

ENDOCRINE:
- Hot flash

HYPERSENSITIVITY:
- Including anaphylaxis

GI:
- Abdominal distention
- C.Diff
- Dyspepsia

NERVOUS SYSTEM:
- Dysarthria
- Fatigue
- Vertigo

HEPATIC:
- Increased ALT
- Increase AST

**FREQUENCY NOT DEFINED:**

CARDIOVASCULAR:
- Prolonged QT interval

GASTROINTESTINGAL:
- Sialorrhea

**MOST COMMON ADVERSE REACTIONS:**

diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, and vulvovaginal candiasis.

## KNOWN DRUG INTERACTIONS

CYP3A4 INHIBITORS → INCREASED GEPOTIDACIN EXPOSURE

CYP3A4 INDUCERS → DECREASE GEPOTIDACIN EXPOSURE

CYP3A4 SUBSTRATES

DIGOXIN

## STORAGE CONSIDERATIONS:

Store at 20°C to 25°C (68°F to 77°F).
- Excursions permitted between 15°C and 30°C (59°F and 86°F).

## PRICING:

$114 per tablet
- Bottle of 8 tablets (~$912 cash price)
- Bottle of 20 tablets (~$2280 cash price)

## BLUEJEPA Coupon

https://blujepa.com/savings/

**Eligible**:
- Patients covered by commercial insurance that does not cover this full cost of BLUJEPA.

**Ineligible**:
- Medicare Part B
- Medicare Part D
- Medicaid
- Medigap
- Veterans Affairs (VA)
- Department of Defense (DoD) programs
- Tricare
- HMO reimbursement plans
- Uninsured Patients

## Thank you!


HannahLewis99@ku.edu

www.linkedin.com/in/hannah-lewis-78893a21b


## SOURCES:


**GlaxoSmithKline LLC. (2026, February). BLUJEPA (gepotidacin) tablets, for oral use: Prescribing information. GSKPro.https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Blujepa/pdf/BLUJEPA-PI-MG.PDF**

**GlaxoSmithKline LLC. (2025). Mechanism of action. BLUJEPA HCP. https://blujepahcp.com/moa/**

**GlaxoSmithKline LLC. (2026). BLUJEPA savings. BLUJEPA. https://blujepa.com/savings-support/savings/**

**GlaxoSmithKline LLC. (2025). BLUJEPA® dosing guide. BLUJEPA. https://blujepa.com/content/dam/brs-pharma-us/blujepa-v2/en_US/resources/pdf/dosing-guide.pdf**

# Lerochol

LERODALCIBEP-LIGA



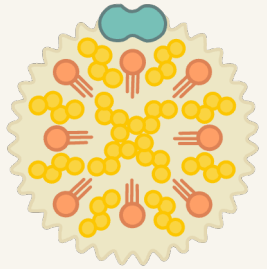
Paige Holopirek
PharmD Candidate 2027
The University of Kansas School of Pharmacy


## Drug Class

PCSK9 Inhibitor

## Mechanism of Action

Lerodalcibep
↓
Binds PCSK9
↓
Prevents PCSK9-LDLR interaction
↓
LDLR preserved and recycled
↓
More LDL receptors on hepatocyte surface
↓
Increased LDL-C uptake
↓
Lower circulating LDL-C



## FDA-Approved Indications

Familial hypercholesterolemia, heterozygous

- Adjunct therapy to maximally-tolerated lipid-lowering agents
- Alternative therapy to patients intolerant of other therapies

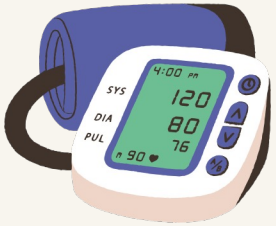
## Areas of Further Research

Elevated Lipoprotein(a) [Lp(a)]

- Lower Lp(a) in patients with high residual cardiovascular risk. Adjunct therapy to maximally-tolerated lipid-lowering agents

Alternative Cardiovascular Events

- Exploring the drug's efficacy in high-risk patients without a history of prior heart attack or stroke

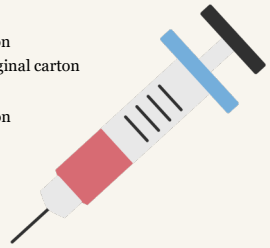



## Dosing

300mg subcutaneously once monthly

## Administration

- Store between 36 - 46 degrees fahrenheit in the original carton
- Room temperature: must be used within 3 months in the original carton
- Do not freeze or shake
- Sit out for 30 minutes after refrigeration before administration
- Sites:
  - Abdomen
  - Upper front thighs
  - Back of upper arms if not self-administered
- Rotate injection site



## Special Populations

**Renal**:
No dosage adjustments necessary

**Hepatic**:
No dosage adjustments necessary

**Pregnancy**:
Discontinue use when pregnant

**Breastfeeding**:
Unknown if present in human milk

## Common Side Effects

- Nose or throat irritation
- Diarrhea
- Upset stomach
- Bruising, itching, pain, redness, swelling, or other reaction where the injection was given

## Severe Side Effects

- Swelling in the arms or legs
- Allergic Reaction

2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/ AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia

4.2.4.3. Severe Hypercholesterolemia With LDL-C ≥190 mg/dL (4.9 mmol/L) → COR 1: If on maximally tolerated statin, addition of:
-Ezetimibe
-PCSK9 mAb
-And/or Bempedoic Acid

4.2.6. Secondary ASCVD Prevention

4.2.7. Management of Adults With Subclinical Coronary Atherosclerosis (Men ≥40 or Women ≥45y) → COR 2a: If on maximally tolerated statin, addition of:
-Ezetimibe
-PCSK9 mAb
-And/or Bempedoic Acid

4.2.8.8. Adults With CKD—Stage 3 or Higher → COR1: High-intensity statin with or without ezetimibe and/or a PCSK9 mAb

4.2.10. Approach to Patients With Elevated Lp(a) → COR1: Maximally tolerated statin can add a PCSK9 mAb

Important to note: Lerochol is not mentioned in the guidelines. "Common" PCSK9 mAbs listed include Alirocumab & Evolocumab

| Feature | Lerochol | Bempedoic Acid | Repatha (evolocumab) | Leqvio (inclisiran) | Ezetimibe | Atorvastatin |
|---|---|---|---|---|---|---|
| Administration | Subcutaneous | Oral | Subcutaneous | Subcutaneous | Oral | Oral |
| Drug Interactions | No significant interactions | Substrate of OAT1/3 Inhibits OATP1B1/1B3 | • Efgartigimod Alfa<br>• Nipocalimab<br>• Rozanolixizumab | No significant interactions | Substrate of OATP1B1/1B3 | Substrate of BCRP, CYP3A4 (Major), NTCP, OATP1B1/1B3, P-glycoprotein (Minor) |
| Dosing adjustments for renal/hepatic function | None | None | None | None | Hepatic Function | Hepatic Function |
| Place in Guidelines | Not stated in guidelines; however, PCSK9-i mAbs are placed below Ezetimibe | Alternative below PCSK9-I mAbs | An example of PCSK9-i mAbs | In same place as PCSK9-i mAbs | First non-statin therapy used | First line in therapy |

Expected outcomes

Prefilled Syringe AWP: $450.00
No coupons; however, manufacturer has direct-to-patient cash-pay option priced at $199 per month

Use in severe refractory cases

Possible utlility in patients with difficulty adhering to daily medications

Further research into Lp(a) benefits could improve value

LEROCHOL™
(lerodalcibep-liga) Injection 300 mg/1.2 mL

# References:


- Grundy SM, Morris PB, Ballantyne CM, et al. 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of dyslipidemia: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2026. doi:10.1161/CIR.0000000000001423.
- Lexi-Drugs. UpToDate Lexidrug. UpToDate, Inc. https://online-lexi-com.www2.lib.ku.edu/lco/action/doc/retrieve/docid/patch_f/7185845?cesid=125yXeKBzUb&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dleqvio%26t%3Dname%26acs%3Dfalse%26acq%3Dleqvio
- LIB Therapeutics, Inc. LEROCHOL (lerodalcibep-liga) for injection. https://www.lerochol.com/
- Novel PCSK9 inhibitor lerodalcibep reduces LDL-C by more than 50% in high-risk patients. The Cardiology Advisor. Published April 2024. https://www.thecardiologyadvisor.com/news/lerochol-pcsk9-inhibitor-ldl-c-reduction/


# Questions?

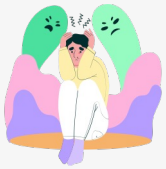
THANK YOU!

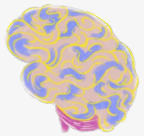

Paige Holopirek
Final-Year PharmD Candidate 2027
The University of Kansas School of Pharmacy


# Bysanti (milsaperidone)


Emily Woods
PharmD Candidate, Class of 2027
University of Kansas School of Pharmacy

# INDICATIONS



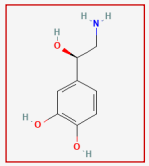


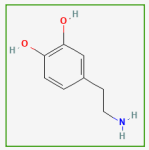
| FDA Approved | Recommended Pharmacotherapy |
|---|---|
| **Bipolar I disorder** | Mood stabilizers<br>Atypical antipsychotics |
| **Schizophrenia** | Atypical antipsychotics |

**Off-label:**
Agitation, anxiety, delirium, insomnia, obsessive compulsive disorder, post-traumatic stress disorder

# MECHANISM OF ACTION

**Neurotransmitter receptor antagonist**



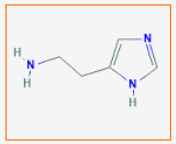


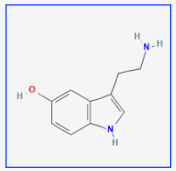
Moderate-Strong affinity:

- **Norepinephrine**
  - $NE_{\alpha1}$, $NE_{\alpha2B}$, $NE_{\alpha2C}$
- **Dopamine**
  - $D_1$, $D_2$, $D_3$, $D_4$
- **Histamine**
  - $H_1$
- **Serotonin**
  - $5\text{-}HT_{1B}$, $5\text{-}HT_{2A}$, $5\text{-}HT_{2C}$

Weak affinity:

- **Norepinephrine**
  - $NE_{\alpha2A}$
- **Serotonin**
  - $5\text{-}HT_{1A}$, $5\text{-}HT_6$





# ADMINISTRATION

| General Population | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | Maintenance |
|---|---|---|---|---|---|---|---|---|
| **Bipolar I Disorder** | 1 mg PO BID | 3 mg PO BID | 6 mg PO BID | 9 mg PO BID | 12 mg PO BID | Titration complete | | 12 mg PO BID |
| **Schizophrenia** | 1 mg PO BID | 2 mg PO BID | 4 mg PO BID | 6 mg PO BID | 8 mg PO BID | 10 mg PO BID | 12 mg PO BID | 6-12 mg PO BID |

*Restart titration if > 3 days of doses are missed*

Main Considerations:

- Titrate to reduce the risk of orthostatic hypotension
- ± food

Additional Considerations:

- CYP2D6 genetic testing
  - Poor metabolizer ⟶ lower maintenance doses
- Hepatic impairment
  - Mild = no adjustments; moderate = lower maintenance; severe = not recommended
- Concomitant CYP2D6 inhibitor and/or CYP3A4 inhibitor


# ADVERSE REACTIONS

**Bipolar mania**

- **Dizziness**
- **Dry mouth**
- Hypotension
- Increased hepatic enzymes*
- Nasal congestion
- Somnolence
- **Tachycardia**
- Weight gain

**Schizophrenia**

- **Dizziness**
- Dry mouth
- Fatigue
- Nasal congestion
- Orthostatic hypotension
- **Somnolence**
- **Tachycardia**
- Weight gain

*Unique based on condition
**Bold** = most common in clinical studies

Others: upset stomach, diarrhea, headache

## COMPARISON TO OTHER SGAs

### Advantages

- Active metabolite of iloperidone
  - In vivo interconversion (dual activity)
- Tolerability:
  - Fewer metabolic disruptions/changes
  - Low risk of EPS (e.g. akathisia, TD)
  - Less sedation

### Disadvantages

- Cost
  - Cheaper alternatives
  - Iloperidone already on the market
- BBW: elderly with dementia-related psychosis
- Initial dose titration + drug-drug interactions
- QTc prolongation

## RESOURCES


American Psychiatric Association. (2020). The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia (3rd ed.). American Psychiatric Association Publishing. https://doi.org/10.1176/appi.books.9780890424841.

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Department of Veterans Affairs & Department of Defense. (2023). VA/DoD clinical practice guideline for management of bipolar disorder. https://www.healthquality.va.gov/guidelines/MH/bd/.

Iloperidone. Lexi-Drugs. UpToDate Lexidrug. UpToDate Inc. https://online.lexi.com. Accessed May 25, 2026.

Haines, S. T., Nolin, T. D., Ellingrod, V. L., Cocohoba, J. M., Holle, L., & Posey, L. M. (2026). DiPiro's pharmacotherapy: A pathophysiologic approach. McGraw Hill.

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Questions?


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# Nereus™ (tradipitant)


**Emily Scott**

PharmD Candidate 2027


## Objectives

By the end of this presentation, you should be able to...

1. Identify the indication of Nereus™
2. Understand the mechanism of action and key adverse effects of Nereus™
3. Discuss dosing and administration considerations with Nereus™
4. Compare Nereus™ with other commonly used antiemetics

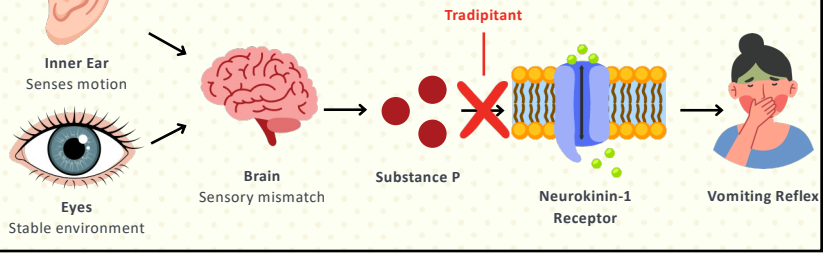
# Approval & Indications

**FDA Approval Date**:
December 30, 2025

**Labeled Indication**:
Prevention of vomiting induced by motion in adults

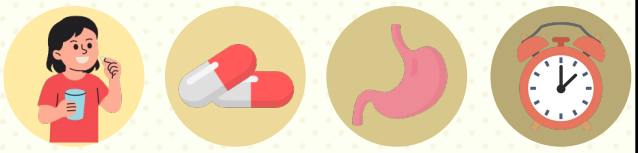
# Mechanism of Action

**Pharmacologic Class**:
Neurokinin-1 Receptor Antagonist




# Dosing & Administration

**Dosing**:
85 or 170 mg orally as a single dose



Use lowest effective dose

Maximum daily dose: single dose of 85 or 170 mg

Take on an empty stomach

Take 60 minutes before triggering event

# Dosing Considerations

**Renal Insufficiency**:
eGFR ≥ 30: No dose adjustment
eGFR < 30: Avoid use

**Hepatic Insufficiency**:
Avoid use in Child-Turcotte-Pugh classes A to C

**Geriatrics**:
No dose adjustments required

**Pregnancy & Lactation**:
Pregnancy: Data insufficient to determine risk
Lactation: Unknown if present in breast milk

# Adverse Effects


Drowsiness


Fatigue


Headache

# Alternatives

| | Nereus™ | Other NK1-RAs | Antihistamines | Scopolamine |
|---|---|---|---|---|
| NT/Receptor Target | Substance P/ NK1 Receptor | Substance P/ NK1 Receptor | Histamine/H1-Receptor | ACh/Muscarinic Receptor |
| FDA Approved for Motion Sickness? | Yes | **No** | Yes | Yes |
| Adverse Effects | CNS Effects | CNS & GI Effects | **Anticholinergic & CNS Effects** | **Anticholinergic & CNS Effects** |

# Pricing

Direct-to-Consumer:
**$85**

Standard List Price:
**$255**

# Thank You

**Emily Scott**
emilyscott@ku.edu

## References

Brainard, Andrew, and Chip Gresham. "Prevention and treatment of motion sickness." American family physician vol. 90,1 (2014): 41-6.

Halpern, Luke. "Tradipitant Becomes First Treatment Approved for Vomiting Due to Motion Sickness in 4 Decades." Pharmacy Times, 2 Jan. 2026, Pharmacy Times. (pharmacytimes.com)

Nereus (tradipitant) [prescribing information]. Washington, DC: Vanda Pharmaceuticals Inc; March 2026

# Zoliflodacin

*NUZOLVENCE*

Makenzie Flax, 2027 PharmD Candidate

## LEARNING OBJECTIVES

1. Identify and review FDA-approved indications for zoliflodacin
2. Review the mechanism of action of zoliflodacin and discuss side effects
3. Examine the dose and the route of administration
4. Compare and contrast zoliflodacin with the current standard of care

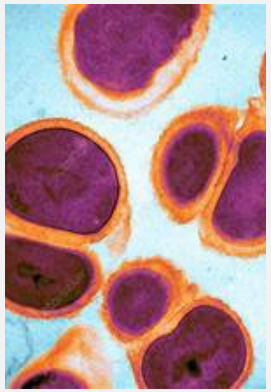


Image: https://www.animalia-life.club/qa/pictures/neisseria-gonorrhoeae-microscope.html

## Indication

- Zoliflodacin is indicated for the treatment of **uncomplicated urogenital gonorrhea** due to *Neisseria gonorrhoeae* in patients > 12 years old and > 35 kg.

## Mechanism of Action

- Zoliflodacin is a spiropyrimidinetrione inhibitor of DNA gyrase and topoisomerase IV. It binds with the cleaved DNA-gyrase complex, blocking re-ligation, and interacts with the conserved amino acids in the gyrase B subunit
- Zoliflodacin has demonstrated activity against drug-resistant *N. gonorrhoeae*

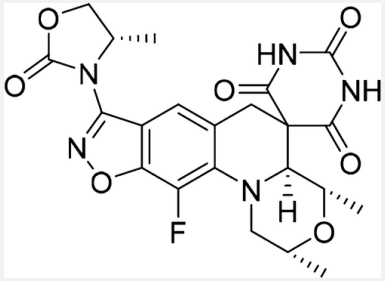



Image: https://pubs.acs.org/doi/10.1021/acsinfecdis.0c00021

## Adverse Effects and Precautions

Adverse effects include: neutropenia (12%); headache (10%); dizziness (3%); nausea (3%); diarrhea (2%)

Zoliflodacin is contraindicated in concomitant use with **moderate or strong CYP3A4 inducers**

- Carbamazepine, rifampin, phenytoin

## Reproduction and Lactation

Based on data from animal studies, zoliflodacin may cause fetal harm at clinically relevant doses

- Patients of reproductive potential should be advised to take a pregnancy test before initiation of zoliflodacin

There may be a risk of early pregnancy loss in female partners of males treated with zoliflodacin

Zoliflodacin may impair male fertility by decreasing spermatogenesis. Testicular toxicity was also observed in animal studies

It is not known if zoliflodacin is present in breast milk

## Dose and Administration

| ADMINISTRATION OF NUZOLVENCE (WITH OR WITHOUT FOOD BASED ON WEIGHT) | | |
|---|---|---|
| **Dose of NUZOLVENCE** | **Body weight** | **Administration of NUZOLVENCE relative to the ingestion of food** |
| 3 g administered as a single, oral dose | ≥35 kg to <50 kg | Take on empty stomach, 1 hour before or 2 hours after food |
| | ≥50 kg | Take with food |

Image: https://www.nuzolvence.com/

- The recommended dose is 3 grams administered orally as a single dose
- Nuzolvence is supplied as a kit containing one unit-dose packet, a mixing container, instructions for use, and a medication guide
- Nuzolvence must be mixed with 60 mL of water. It cannot be mixed with other liquids or sprinkled on food
  - Once the suspension is uniform, the entire contents must be administered within 15 minutes of mixing

## Patient Counseling Points

- Advise male patients with female partners of reproductive potential to use effective contraception for at least **3 months** after receiving zoliflodacin
- Zoliflodacin granules must be mixed with water for consumption. Do not take granules in the dry form
- Patients weighing 50 kg (110 lbs) or more should take zoliflodacin with food

Image: https://img.magnific.com/premium-photo/pharmacy-medication-pharmacist-explaining-prescription-female-patient-chemist-pharmaceutical-dispensary-male-healthcare-worker-talking-about-medicine-woman-drug-store_590464-137053.jpg?w=2000

## Zoliflodacin vs Comparators

Zoliflodacin was studied in a randomized, open-label, active-controlled, multicenter trial

Patients were randomized to receive a single 3-gram dose of zoliflodacin or a combination of a single 500 mg intramuscular dose of ceftriaxone with a single 1-gram oral dose of azithromycin

Results of the studies showed that zoliflodacin was **non-inferior** to ceftriaxone plus azithromycin for the treatment of uncomplicated urogenital gonorrhea and had a similar safety profile

## Zoliflodacin vs Comparators

**Similarities:**

- Both zoliflodacin and ceftriaxone plus azithromycin are one-time doses

**Pros of zoliflodacin:**

- Self-administration
- Similar test-of-cure rates to ceftriaxone plus azithromycin
- Good safety profile
- No injections

**Cons of zoliflodacin:**

- Cost and accessibility barriers
- Fertility risks

# Questions?

Email: makenzie.flax@ku.edu

## References


- https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/219491Orig1s000lbl.pdf
- https://www.nuzolvence.com/#ISI2
- https://pubmed.ncbi.nlm.nih.gov/41391465/
- https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4beda35a-21b0-4b34-84ea-be6ea8cae50f

# POST-TEST

1. What is the mechanism of action of Blujepa?
   a. Spiropyrimidinetrione inhibitor which inhibits type II topoisomerases
   b. Triazaacenephthylene antibacterial which inhibits type II topoisomerases
   c. Inhibits protein synthesis by binding to the 30s ribosomal subunit
   d. Inhibits protein synthesis by binding to the 50s ribosomal subunit

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# POST-TEST

2. What is the approved indication for Bysanti?
   a. Moderate to severe vasomotor symptoms due to menopause
   b. Prevention of motion-induced vomiting in adults
   c. Bipolar I disorder and schizophrenia
   d. Familial hypercholesterolemia, heterozygous

# POST-TEST

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# POST-TEST

3. Lynkeut is contraindicated in those with severe renal impairment
   - True
   - False

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# POST-TEST

3. Lynkeut is contraindicated in those with severe renal impairment
   - True
   - **False**

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# POST-TEST

4. Which is true regarding the administration of Nereus?
   a. It should be taken with food
   b. It should be taken at the onset of motion sickness
   c. It should be taken one hour before a triggering event
   d. Patients may take up to 2 capsules (170 mg) as needed for motion-induced vomiting

# POST-TEST

4. Which is true regarding the administration of Nereus?
   a. It should be taken with food
   b. It should be taken at the onset of motion sickness
   **c. It should be taken one hour before a triggering event**
   d. Patients may take up to 2 capsules (170 mg) as needed for motion-induced vomiting

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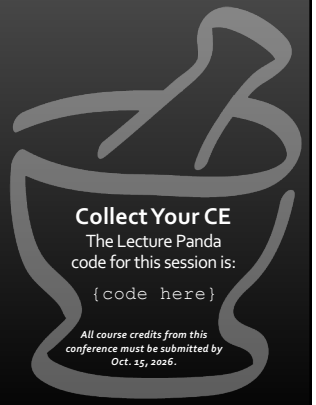
# THANK YOU!



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