KPhA New Drugs 2025

University of Kansas
Student Pharmacists

Kentucky Pharmacy Education and Research Foundation, Inc. is accredited by ACPE as a provider of continuing pharmacy education.

ACPE UAN 0143-9999-25-076-L01-P/T

Kansas Pharmacists Association // 2025 Annual Meeting & Trade Show August 22-24 // Lawrence, KS

DISCLOSURES

Faculty

Amanda Applegate, faculty for this activity, is a committee member of Sunflower Health Plan's Quality Improvement Committee and the relationship has been mitigated through review.

Planners

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

THANK YOU!

Student Presenter	Pharmacist Reviewer
Madison Shotton	Tyler Williams
Mary Fritz	Megan Klatt
Joelle Frady	Rachel Jankowski
Paige Holopirek	Abby Petrulis
Emma Schultz	Ashley Crowl-Glissman
Adison Hoppas	Megan Martin
Emily Scott	Cole Kendall

Kansas Pharmacists Association // 2025 Annual Meeting & Trade Show August 22-24 // Lawrence, KS

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.

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PRE-TEST

1. What is the FDA approved indication for use of Revumenib?

A. ER+, HER2- breast cancer
B. Advanced ovarian cancer
C. Acute relapsed or refractory leukemia caused by the translocation of the KMT2A gene
D. Acute relapsed or refractory Hodgkin lymphoma

PRE-TEST

2. What is an advantage of using suzetrigine (Journavx)?

A. It is a well-established therapy and shows superiority to opioids
B. It may be used for chronic or acute pain
C. Although it is a controlled substance, it doesn't show signs of addiction
D. It is not an opioid or controlled substance, is generally well-tolerated, and useful for acute pain

Zunvey

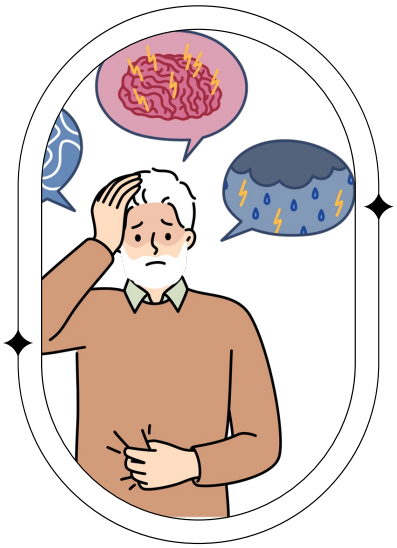
(benzgalantamine)

Presented by:
Madison Shotton (P4)

Indications

Alzheimer's Disease (mild to moderate)

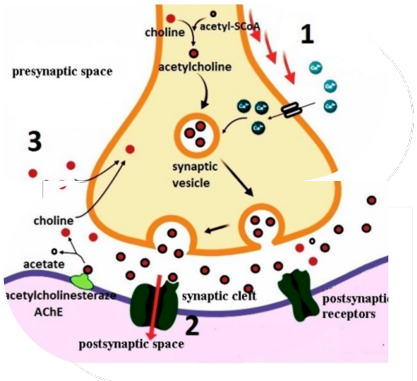
- Progressive brain disorder that primarily affects memory, thinking, and reasoning skills, leading to a decline in daily life activities.
- No known cure
- Staged using the Alzheimer's Disease Assessment Scale –Cognitive section (ADAS-Cog)



Kueper JK, Speechley M, Montero-Odasso M. The Alzheimer's Disease Assessment Scale–Cognitive Subscale (ADAS-Cog): Modifications and Responsiveness in Pre-Dementia Populations. A Narrative Review. J Alzheimers Dis.

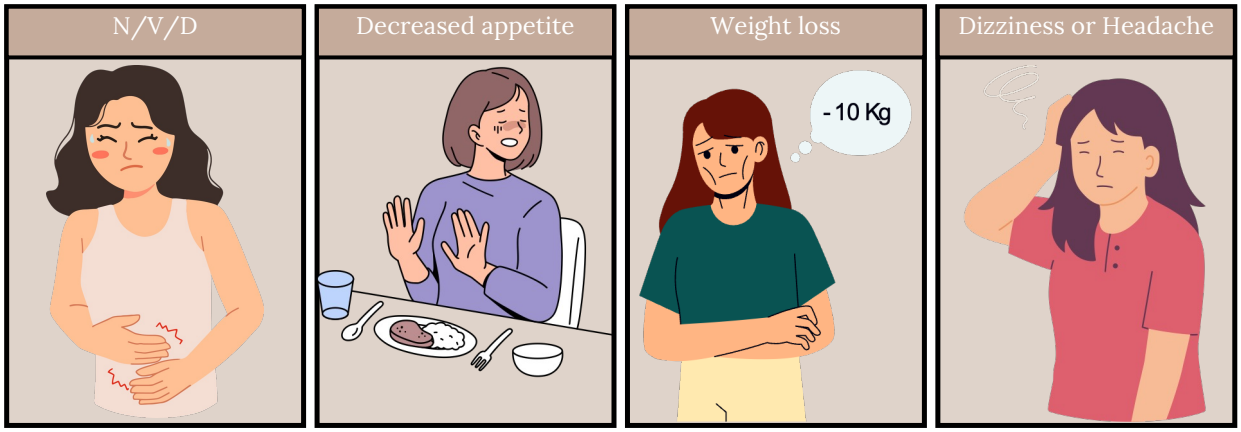
Mechanism of Action

- Prodrug of galantamine - metabolized by CYP2D6
- Cholinesterase inhibitor (competitive and reversible)
- Increases acetylcholine by slowing the degradation*



***does not reverse the effects of Alzheimer's**

Adverse Effects



Many people have none or very minor side effects. Less than 5% of patients experienced these.

Dosage and Administration

Initial Dosing*

May increase dose based on response and tolerability in 10 mg/day increments (divided twice daily) at intervals ≥4 weeks, up to a maximum dose of 30 mg/day (divided twice daily).

5 mg twice daily x 4 weeks → **10 mg twice daily x 4 weeks** (maintenance dose) → 15 mg twice daily x 4 weeks

*dosage adjustments for kidney and liver impairment

Administration

Delayed release oral tablets

BID with or without food

Do NOT split, crush, or chew

Stay hydrated

Comparison

Benzgalantamine (Zunveyl)

Features

- Cholinesterase Inhibitor
- Oral tablet only
- Prodrug
- No generic available
- BID dosing
- With or without food
- Renal adjustment
- Minimal adverse effects
- Treats mild-moderate AD

Donepezil (Aricept)

Similarities

- ✓ Cholinesterase Inhibitor
- ✓ Oral tablet available
- ✓ CYP2D6 substrate

Differences

- ✗ Generic available
- ✗ Transdermal patch
- ✗ More adverse effects
- ✗ No renal adjustment
- ✗ Can treat severe AD

Rivastigmine (Exelon)

Similarities

- ✓ Cholinesterase Inhibitor
- ✓ Oral capsule available
- ✓ BID dosing

Differences

- ✗ Generic available
- ✗ Transdermal patch
- ✗ More adverse effects
- ✗ No renal adjustment*
- ✗ Can treat severe AD + more

*patch only

Galantamine (Razadyne ER)

Similarities

- ✓ Cholinesterase Inhibitor
- ✓ Oral tablet available
- ✓ CYP2D6 substrate
- ✓ Renal adjustment required
- ✓ Treats mild-moderate AD

Differences

- ✗ More adverse effects
- ✗ Generic available
- ✗ Additional indications

Thanks for listening!

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ZEVTERA®

CEFTOBIPROLE MEDOCARIL

PRESENTED BY: MARY FRITZ, PHARMD.
CANDIDATE CLASS OF 2026

WHAT IS ZEVTERA®?

- Ceftobiprole is a 5th generation cephalosporin
- Formulated as ceftobiprole medocaril (prodrug) that is converted to ceftobiprole (active moiety)
- Mechanism of action: Inhibition of cell wall synthesis via binding to penicillin binding proteins (PBPs)
- Special Qualities: High affinity for *S. aureus* PBPs 1-4 including PBP2a (*methicillin-resistant S. aureus* (MRSA)), PBP2x/b (penicillin-resistant *S. pneumoniae)*

USDA. 2024. Zevtera. FDA. Retrieved 06/17/2025 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218275s000lbl.pdf

SPECTRUM OF ACTIVITY

- Gram-Positive Bacteria:
- *Staphylococcus aureus* (including MRSA), coagulase-negative *Staphylococcus spp.*, and *Streptococcus spp.*
- Gram-positive anaerobes

- Gram-Negative Bacteria:
- Species-dependent activity
- No activity against extended-spectrum beta-lactamase (ESBL)- and carbapenemase-producing organisms

USDA. 2024. Zevtera. FDA. Retrieved 06/17/2025 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218275s000lbl.pdf

INDICATIONS FOR USE

- Adult patients with Staphylococcus aureus bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis
- Adult patients with acute bacterial skin and skin structure infections (ABSSSI)
- Adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP)

USDA. 2024. Zevtera. FDA. Retrieved 06/17/2025 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218275s000lbl.pdf

SPECIFIC DOSING AND ADVERSE SIDE EFFECTS

ADULT DOSING:

Indication in Adults	Dose	Frequency
SAB	667 mg	Every 6 hours on Days 1-8
		Every 8 hours on Days 9 onward
ABSSSI	667 mg	Every 8 hours
CABP	667 mg	Every 8 hours

- Duration of treatment: Up to 42 days for SAB, 5-14 days for ABSSI and CABP
- Administer infusion over 2 hours

USDA. 2024. Zevtera. FDA. Retrieved 06/17/2025 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218275s000lbl.pdf

PEDIATRIC DOSING:

Pediatric Age Group for CABP	Dose	Frequency
12 years to less than 18 years old	13.3 mg/kg (up to 667 mg per dose)	Every 8 hours
Greater than or equal to 3 months and less than 12 years old	20 mg/kg (up to 667 mg per dose)	Every 8 hours

- Duration of treatment: 7-14 days
- Administer infusion over 2 hours

USDA. 2024. Zevtera. FDA. Retrieved 06/17/2025 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218275s000lbl.pdf

DOSING CONSIDERATIONS

- Reduce the dosage in adult patients with CrCl < 50 mL/min, including patients with a CrCl < 15 mL/min on hemodialysis
- Increase the dosage in adult patients with CrCl > 150 mL/min
- Reduce the dosage in pediatric patients aged 2 years old < 18 years old with eGFR < 50 mL/min/1.73 m^2 and >/= to 15 mL/min/1.73 m^2

USDA. 2024. Zevtera. FDA. Retrieved 06/17/2025 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218275s000lbl.pdf

SIDE EFFECT PROFILE

Most common side effects (> 10%):

- Gastrointestinal upset (nausea/vomiting/diarrhea)
- Anemia

Other side effects (1 – 10%):

- Hypersensitivity reactions (swelling, anaphylaxis, etc.)
- Injection site reactions
- Increased serum creatinine
- Increased liver enzymes

(2025, May 28). *Zevtera: Ceftobiprole Medocaril* [Review of *Zevtera: Ceftobiprole Medocaril*]. Lexicomp; Lexicomp UpToDate. https://online-lexi-com.www2.lib.ku.edu/lco/action/doc/retrieve/docid/patch_f/1266541?cesid=44AzuWq2kvw&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dzevtera%26t%3Dname%26acs%3Dfalse%26acq%3Dzevtera#gdr

CEFTOBIPROLE VS. CEFTAROLINE

CEFTOBIPROLE VS. CEFTAROLINE INDICATIONS

Ceftobiprole	Ceftaroline
SAB	ABSSSI
ABSSSI	CABP
CABP	

- Both agents are 5th generation cephalosporins
- Ceftaroline is typically used as combination therapy with another MRSA agent (i.e., vancomycin or daptomycin) to assist with blood culture clearance

(2025, May 28). *Zevtera: Ceftobiprole Medocaril* [Review of *Zevtera: Ceftobiprole Medocaril*]. Lexicomp; Lexicomp UpToDate. https://online-lexi-com.www2.lib.ku.edu/lco/action/doc/retrieve/docid/patch_f/12665412?cesid=44AzuWq2kvw&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dzevtera%26t%3Dname%26acs%3Dfalse%26acq%3Dzevtera#qdr

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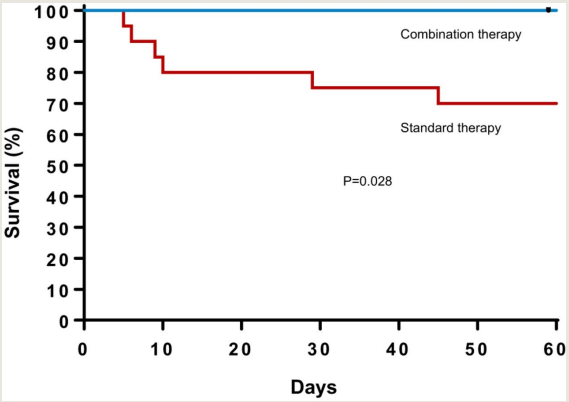
CLINICAL DATA ON DAPTOMYCIN PLUS CEFTAROLINE

- Pilot study of adult patients with MRSA bacteremia randomized to combination of daptomycin plus ceftaroline or monotherapy with vancomycin or daptomycin
- 40 patients included (17 patients on combination therapy, 21 patients with vancomycin monotherapy, 3 patients with daptomycin monotherapy)
- In-hospital mortality occurred in zero patients in combination therapy arm compared to 26% of patients on monotherapy resulted in study termination
- Additional studies support the benefit of combination therapy for MRSA bacteremia



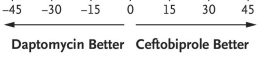
Geriak, M., Haddad, F., Rizvi, K., Rose, W., Kullar, R., LaPlante, K., Yu, M., Vasina, L., Ouellette, K., Zervos, M., Nizet, V., & Sakoulas, G. (2019). Clinical Data on Daptomycin plus Ceftaroline versus Standard of Care Monotherapy in the Treatment of Methicillin-Resistant Staphylococcus aureus Bacteremia. *Antimicrobial Agents and Chemotherapy*, *63*(5). https://doi.org/10.1128/aac.02483-18

CEFTOBIPROLE FOR TREATMENT OF COMPLICATED *STAPHYLOCOCCUS AUREUS* BACTEREMIA

- Phase 3, randomized, double-blind, non-inferiority study of adults with complicated *S. aureus* bacteremia comparing ceftobiprole versus daptomycin (plus optional aztreonam)
- 390 patient included (189 patients with ceftobiprole and 198 patients with daptomycin)
- Primary outcome of treatment success was similar between groups (69.8% vs. 68.7%)
- Study led to FDA approval of the drug as monotherapy for MSSA and MRSA bacteremia

Holland, D., Cosgrove, S. E., Doernberg, S. B., Jenkins, T. C., Turner, N., Boucher, H. W., Pavlov, O., Titov, I., Serhii Kosulnykov, Boyko Atanasov, I Poromanski, Manana Makhviladze, Anderzhanova, A., Stryjewski, M. E., Maziar Assadi Gehr, Engelhardt, M., Hamed, K., Ionescu, D., Jones, M., & Mikaël Saulay. (2023). Ceftobiprole for Treatment of Complicated *Staphylococcus aureus* Bacteremia. *The New England Journal of Medicine*, *389*(15). https://doi.org/10.1056/nejmoa2300220

Subgroup	Ceftobiprole	Daptomycin	Percentage-Point Difference (95% CI)
	no. of patients/total no. (%)		
All patients	132/189 (69.8)	136/198 (68.7)	2.0 (−7.1 to 11.1)
Age at written informed consent			
18 to <65 yr	98/131 (74.8)	101/135 (74.8)	0.6 (−9.8 to 10.9)
≥65 yr	34/58 (59)	35/63 (56)	6.9 (−10.5 to 24.3)
Sex			
Male	93/128 (72.7)	92/140 (65.7)	8.0 (−2.8 to 18.8)
Female	39/61 (64)	44/58 (76)	−11.3 (−27.7 to 5.1)
Baseline category of complicated *S. aureus* bacteremia			
Soft-tissue infection	81/116 (69.8)	80/121 (66.1)	4.5 (−7.3 to 16.3)
S. aureus bacteremia excluding soft-tissue infection	51/73 (70)	56/77 (73)	−1.7 (−15.9 to 12.6)
Osteoarticular infection	23/32 (72)	24/35 (69)	2.9 (−19.7 to 25.6)
Abdominal abscess	18/26 (69)	22/29 (76)	−9.7 (−33.3 to 13.9)
Hemodialysis	13/24 (54)	15/25 (60)	−4.6 (−32.5 to 23.3)
Persistent *S. aureus* bacteremia	8/16 (50)	8/16 (50)	−0.0 (−35.9 to 35.9)
Infective endocarditis on right side of heart	10/15 (67)	7/10 (70)	−6.6 (−40.1 to 27.0)
Baseline *S. aureus* infection			
Methicillin-susceptible	100/141 (70.9)	97/146 (66.4)	4.8 (−5.9 to 15.5)
Methicillin-resistant	31/45 (69)	38/49 (78)	−8.3 (−25.3 to 8.6)
Previous antibiotic use			
Yes	92/139 (66.2)	85/134 (63.4)	2.9 (−8.4 to 14.2)
No	40/50 (80)	51/64 (80)	−0.2 (−15.0 to 14.6)
Trial cohort			
Cohort 1	68/97 (70)	62/96 (65)	7.6 (−5.6 to 20.8)
Cohort 2	64/92 (70)	74/102 (72.5)	−3.4 (−16.1 to 9.3)



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THANK YOU

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REVUMENIB (REVUFORJ)

Joelle Frady
PharmD Candidate 2026

OBJECTIVES

- Identify indications for revumenib
- Identify mechanisms of action and key adverse events of revumenib
- Identify the route of administration and key considerations regarding dosage and administration of revumenib
- Compare revumenib agents with older medications and/or identify the most important advantages and disadvantages of its use

WHAT IS REVUMENIB?

First-in-class oral **menin inhibitor** for those at least **1 year of age** with **acute relapsed or refractory leukemia** caused by translocation of the **KMT2A gene**

WHAT IS MENIN?

- **KMT2A translocations** allow **menin** to drive cancer growth
- Menin is a **tumor suppressor** that interacts with chromatin and drives the expression of HOX and MEIS1 genes, which **promotes proliferation of undifferentiated cells**
- **Revumenib blocks** interactions between **menin** and other **proteins** to inhibit this uncontrolled growth

Note: KMT2A is considered an intermediate risk genetic mutation for AML

BEFORE ADMINISTRATION

Cannot initiate until:
- WBC < 25,000/mm3
- Electrolyte abnormalities (Mg, K) are corrected

Do not initiate if:
- QTcF > 450ms using Fredericia formula

Pregnancy considerations:
- may cause fetal harm based on animal reproductive studies

Breastfeeding considerations:
- not recommended during treatment and for 1 week after last dose

Contraception considerations:
- use effective contraception during therapy and for 4 months after

HOW TO DOSE REVUMENIB:

dosing of revumenib is dependent on **patient's weight,** use with strong **CYP3A4 inhibitors**, and **BSA**

Patient Wei
≥ 40kg
≥ 40kg
< 40kg

*calculate BSA using Mostseller formula

DURATION:

recommend a minimum of **6 months** without progression or toxicity

DOSING CONSIDERATIONS

Administration
- Take in fasted state or with a low-fat meal (~ 400 calories, < 25% fat)
- Swallow whole, do not cut or chew
- May crush and disperse in ~10 mL water

Altered Kidney Function
- None recommended by the manufacturer due to lack of being studied

Altered Liver Function
- None recommended by the manufacturer due to lack of being studied

Obesity
- Use recommended FDA-approved dosing without changes
- Manage systemic toxicities the same

Toxicity
- Consider further dose reductions from recommended manufacturer dosing if toxicity occurs

MONITORING PARAMETERS

CBC

Do not initiate until WBC < 25,000/m3 and monitor CBC **monthly**

Electrolytes

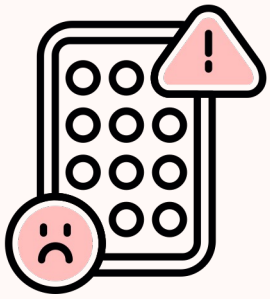
Monitor electrolytes, specifically magnesium and potassium, at least **monthly**

LFTs

Monitor LFTs at least **monthly**

EKG

Monitor prior to initiation, at least **once weekly** for the first four weeks, and then **monthly**



ADVERSE EVENTS

Black Box Warning: Differentiation Syndrome

- rapid release of cytokines from leukemia cells
- symptoms: fever, dyspnea, hypoxia, peripheral edema, pleuropericardial effusion, acute renal failure, hypotension

Adverse drug reactions:

- Hypomagnesemia
- Hypokalemia
- Neutropenia
- Thrombocytopenia
- Leukocytosis
- QTc prolongation

ALTERNATIVE AGENTS FOR AML

Targeted agents for AML:

Gliteritinib, Quizartinib (Oral) - FLT3 target
Azacitidine (SQ/IV) - FLT3 target
Enasidenib (Oral) - IDH2 target
Ivosidenib (Oral) - IDH1 target
Olutasidenib (Oral) - IDH1 target
Gemtuzumab ozogamicin (IV)- CD33 target

Chemotherapy for relapsed AML:

Combination antimetabolites + antineoplastic + G-CSF
Cytarabine + anthracyclines
Combination antimetabolites
Etoposide + antimetabolite
Azacitidine or decitabine

COMPARISON OF AGENTS

Revumenib

- Oral administration decreases risk of infection from a chemotherapy port
- Single agent therapy
- Black Box Warning: Differentiation Syndrome
- Side effect monitoring:
  - EKG, CBC, LFTs, Mg, K
- Possibility for drug-drug interactions, especially with CYP3A4
- High incidence of nausea or other GI disturbances
- No indication for G-CSF
- Multiple strengths may be required to reach target dose

Traditional chemotherapy

- IV or SQ administration
- Combination therapy increases risk for adverse reactions and myelosuppression
- Potential maximum doses reached with anthracyclines
- Black box warnings vary:
  - Cardiomyopathy
  - Bone marrow suppression
  - Secondary cancers
- Side effect monitoring depends on the regimen, but may include:
  - EKG, CBC, LFTs, electrolytes, Scr

COST & ACCESSIBILITY

Out-of-pocket Cost: $39,000 - $45,000 (30-day supply)

Products: 25mg tablet, 110mg tablet, 160mg tablet

- multiple strengths may be needed to supply intended dosing

Copay Assistance Programs

Revuforj Copay Program: eligible patients may pay as little as $0 per prescription

- excludes cash-paying patients
- excludes Medicare parts A-D
- excludes Medicaid
- excludes TriCare, VA, DoD

Leukemia & Lymphoma Society (www.lls.org)

- may provide assistance towards private, Medicare, Medicaid, & Tricare premiums

American Cancer Society (800-227-2345)

CancerCare (cancercare.org)

Patient Advocate Foundation (copays.org)

DRUG CONSIDERATIONS

- **Drug Interactions with:**
  - CYP3A4 inhibitors
  - QTc prolonging medications
  - Any immunosuppressant or myelosuppressant
- **Interactions with live vaccines**
- **Allogeneic stem transplant** remains the only cure to AML

REFERENCES

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- https://revuforj.com/
- https://clinicaltrials.gov/study/NCT05761171
- https://syndaccess.com/
- https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf

THANK YOU!
QUESTIONS?

Sofdra

Sofpironium

Paige Holopirek

Overview

Drug Class: Anticholinergic Agent

Indications: Primary Axillary Hyperhidrosis

Formulation: Topical gel

Counseling Points

- Alert your doctor if you are not sweating in high heat/exercising
- Do not shave armpits or use deodorant in your armpits for at least 8 hours before putting this drug on.
- Do not shower, wash your underarms, or exercise within 30 minutes before putting this drug on.
- Let skin dry for at least 5 minutes before covering with clothing.

Application

Dosing:

Adult: Apply a single pump actuation to each armpit once daily at bedtime.

Pediatric (≥ 9 years old): Apply 1 pump to dry clean skin on each underarm using the supplied applicator at bedtime; do not apply to other areas or more frequently than once daily.

Route:

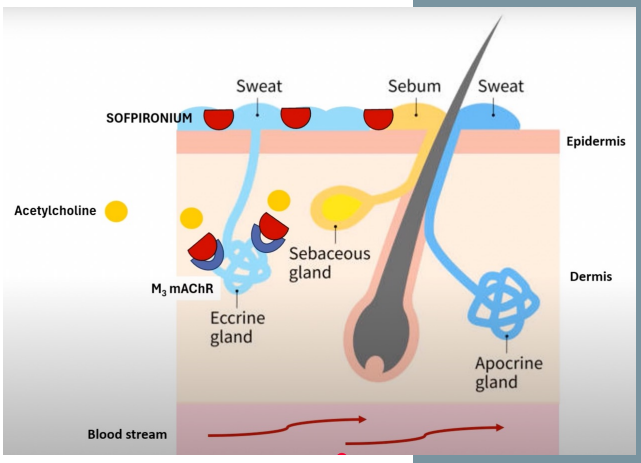
Topical only; do not ingest

Administration:

Wait ~5 minutes to fully dry before putting on clothes. Be aware of flammability.

Mechanism of Action

Competitive inhibitor of acetylcholine receptors located on certain peripheral tissues, including sweat glands; reduces sweating by inhibiting the action of acetylcholine on sweat glands.



Key Adverse Effects

Common:
- Local Axillary Irritation
  - Pain (15%)
  - Itching (15%)
  - Redness (8%)
- Mydriasis (5%)
- Dry eye (4%)
- Dry Mouth (2%)

More Severe:
- Trouble passing urine (4%)
  - pain when passing
  - weak stream or drips
- Larger pupils
- Blurred eyesight
- High body temperature
- Heat stroke
- No sweat during activities or high temperature
- Allergic reaction

Drug Interactions:
- Substrate
  - CYP2D6 (Major)
  - CYP3A4 (Minor)

Contraindications:
- Medical Conditions:
  - Glaucoma
  - Paralytic ileus
  - Myasthenia gravis
  - Sjögren syndrome
  - Severe ulcerative colitis

Comparison to previous therapies

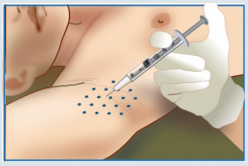
Topical Antiperspirants

- Cheaper
- Shorter Effect
- Staining
- Not permanent solution
- Underarm discoloration

Oral Anticholinergics

- Increased systemic effects
  - Good & Bad
- Convenient
- Fewer risks of administration error
- Dose-dependent effects
- Management only

Botox Injections



- Semi-permanent solution
- Adherence Improvements
- Expensive
- Concern with heat tolerance
- Insurance coverage issues

Expected Outcomes

Advantages:

- Less systemic effects
- Relatively inexpensive ~$30
- Easy to apply
- Effective

Disadvantages:

- Anticholinergic
- Management ONLY
- Will insurance pay?
- Potential drug interaction

Thank you

JOURNAVX™

(suzetrigine) 50mg tablet

EMMA SCHULZ
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DRUG INFORMATION

Brand Name: JOURNAVX

Generic Name: Suzetrigine

FDA Approval: January 2025

Manufacturer: Vertex Pharmaceuticals

Dosage Form: Oral tablets (50 mg)

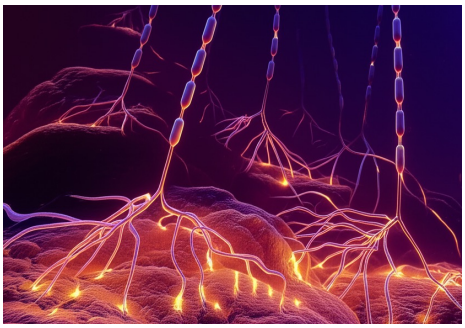
INDICATION

Treatment of moderate to severe acute pain in adults.

Oral nonopioid that reduces pain signals before they reach the brain.

MECHANISM OF ACTION

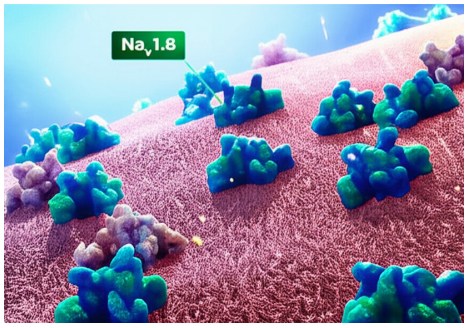
1. **Nociceptors in the PNS detect noxious stimuli and generate action potentials that travel to the CNS, where the brain perceives them as pain.**



PNS: Peripheral Nervous System
CNS: Central Nervous System

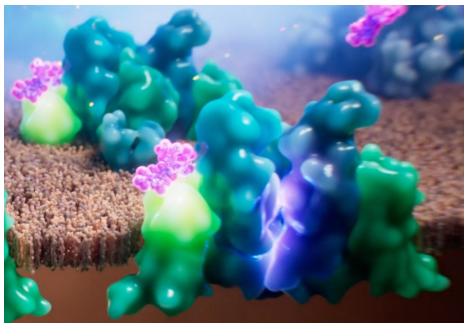
MECHANISM OF ACTION

2 **Journavx selectively blocks Nav1.8 to prevent an action potential and inhibit the transmission of pain signals to the spinal cord and brain.**



MECHANISM OF ACTION

3 **Nav1.8 is expressed in peripheral nociceptive neurons and not the brain. Journaxv also does not interact with μ receptors that are associated with addiction.**



DOSAGE & ADMINISTRATION

Loading Dose:
Take 2 tablets (100 mg) orally once on an empty stomach at least 1 hour before or 2 hours after food.

Maintenance Dose:
Take 1 tablet (50 mg) orally 12 hours after the loading dose and continue every 12 hours, with or without food.

DOSAGE & ADMINISTRATION

Do not crush or chew.

Avoid food or drink containing grapefruit.

Use for the shortest duration consistent with treatment goals. Use has not been studied beyond 14 days.

Guidance on missed doses depends on the maintenance dose and number of missed doses.

DOSE ADJUSTMENTS

Hepatic Impairment

- **Severe (Child-Pugh Class C): Avoid use**
- **Moderate (Child-Pugh Class B): Reduce Journavx dose**
- **Mild (Child-Pugh Class A): No dose adjustment needed**

Renal Impairment

- **Avoid use in patients with an eGFR < 15 mL/min**

ADVERSE EFFECTS

Most Common

Pruritus, muscle spasms, increased blood CPK, rash

Warnings & Precautions

CYP3A substrates, hormonal contraceptives containing progestins other than levonorgestrel and norethindrone

Contraindications

Strong CYP3A4 inhibitors

OTHER TREATMENTS

Opioids
ex. hydrocodone/APAP, oxycodone

Other OTCs
ex. acetaminophen, lidocaine

Nonpharmacological
ex. heat/cold therapy, exercises

NSAIDs
ex. ibuprofen

Inpatient Options
ex. nerve block

PROS & CONS

Advantages

- Not an opioid or controlled substance
- Generally well-tolerated
- Useful for acute pain

Disadvantages

- New drug
- Did not show superiority to an opioid
- No specific antidote available for overdose

SOURCES

Vertex Pharmaceuticals Incorporated (2025). *JOURNAVX™ (suzetrigine) for Moderate-to-Severe Acute Pain*. JOURNAVX™. https://www.journavx.com

Vertex Pharmaceuticals Incorporated (2025). *Healthcare Professionals: JOURNAVX™ (suzetrigine) for Moderate-to-Severe Acute Pain*. JOURNAVX™. https://www.journavxhcp.com

Cleveland Clinic (2025). *Pain Medications After Surgery: Types, Benefits & Risks.* Cleveland Clinic. https://my.clevelandclinic.org/health/articles/11307-pain-control-after-surgery

ZEPBOUND
(TIRZEPATIDE)

Adison Hoppas
PharmD Candidate 2026
University of Kansas School of Pharmacy

MECHANISM OF ACTION

GLP-1/GIP Receptor Agonist

- ↑glucose-dependent insulin secretion
- ↓inappropriate glucagon secretion
- Slows gastric emptying
  - Effectively reduce calorie intake and regulate appetite → reduce body weight

INDICATIONS

- **Moderate-to-Severe Obstructive Sleep Apnea (OSA)**
  - Zepbound is the first and only pharmaceutical treatment approved for moderate-to-severe OSA **in adults with obesity** in combination with a reduced-calorie diet and increased physical activity
- Weight Reduction

DOSING

INITIAL

2.5mg SQ once weekly

MAINTENANCE

10/15mg SQ once weekly

*INCREASE DOSE IN 2.5 MG/WEEK INCREMENTS EVERY 4 WEEKS

DOSAGE FORMS/STRENGTHS

- **Pre-filled single-dose pens/ single-dose vials**
  - 2.5 mg/0.5 mL
  - 5 mg/0.5 mL
  - 7.5 mg/0.5 mL
  - 10 mg/0.5 mL
  - 12.5 mg/0.5 mL
  - 15 mg/0.5 mL

ADMINISTRATION PEARLS

01. ADMINISTER BY SUBQ INJECTION INTO THE ABDOMEN, THIGH, OR UPPER ARM

02. ROTATE INJECTION SITES WITH EACH DOSE

03. SINGLE-DOSE PENS DO NOT REQUIRE PRIMING BEFORE INJECTION

04. PENS/VIALS MAY BE STORED AT ROOM TEMPERATURE FOR UP TO 21 DAYS

ADVERSE EVENTS

- Dyspepsia & Abdominal Pain
- Diarrhea & Constipation
- Injection Site Reactions & Fatigue
- Nausea & Vomiting
- **Precautions**
  - Gallbladder Disease
  - Pancreatitis
  - Acute Kidney Injury

CONTRAINDICATIONS:

- A PERSONAL/FAMILY HISTORY OF **MEDULLARY THYROID CARCINOMA** OR IN PATIENTS WITH **MULTIPLE ENDOCRINE NEOPLASIA SYNDROME TYPE 2** (MEN 2)

COUNSELING PEARLS

POTENTIAL ORAL HORMONAL CONTRACEPTION INTERACTION

INJECTION TECHNIQUE

STORAGE

ALTERNATIVES

- <u>**First and only pharmaceutical treatment**</u>
  - **HOWEVER**, weight reduction alternatives, generally, include:
    - **Wegovy** (semaglutide)
    - **Saxenda** (liraglutide)
      - GLP-1 RA
- Continuous positive airway pressure (**CPAP**) - **Gold Standard**
- Oral applicances

PROS:

- Improved adherence
- Cardiovascular benefits
- Weight reduction

CONS:

- Cost
- Supply
- GI side effects

QUESTIONS?

Adison Hoppas

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REFERENCES

Tirzepatide. *Lexi-Drugs.* UpToDate Lexidrug. UpToDate Inc. https://online.lexi.com. Accessed May 26, 2026.

Zepbound. Prescribing Information. Lilly USA, LLC.

Cobenfy™ (xanomeline/trospium)

Emily Scott, Third-Year Student Pharmacist

Disclosure

I have no conflicts of interest to disclose.

Objectives

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

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

Approval & Indications

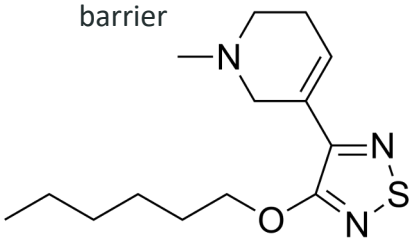
- **FDA Approval Date**: September 26, 2024
- **Labeled Indication**: Treatment of schizophrenia in adults

Mechanism of Action

Cobenfy™ is a first-in-class M1/M4 muscarinic agonist:

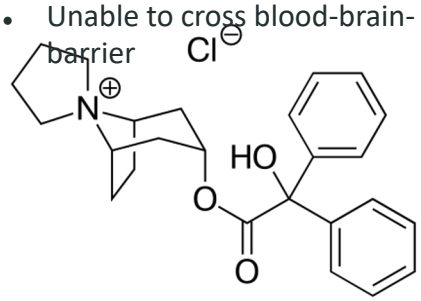
Xanomeline: M1/M4 muscarinic acetylcholine receptor agonist

- Able to cross blood-brain-barrier



Trospium: Muscarinic acetylcholine receptor antagonist

- Unable to cross blood-brain-barrier



* The reason for its efficacy in the treatment of schizophrenia is unclear

Dosing

Route of Administration: Oral

Initial Dosing	Maintenance Dosing	Maximum Dosing
Xanomeline 50 mg and trospium chloride 20 mg twice daily for ≥ 2 days	Xanomeline 100 mg and trospium chloride 20 mg twice daily for ≥ 5 days	Xanomeline 125 mg and trospium chloride 30 mg twice daily

Dosing & Administration Considerations

Administration:

- ≥ 1 hour before meals or ≥ 2 hours after meals
- Do not open capsules

Special Considerations:

- **Geriatrics**: Consider slower titration schedule. Max dose: xanomeline 100 mg / trospium chloride 20 mg
- **Renal Insufficiency**: Not recommended if eGFR < 60 mL/minute
- **Hepatic Insufficiency**: Not recommended if mild impairment; contraindicated in moderate to severe impairment

Common Adverse Effects

Cardiovascular: Hypertension

Gastrointestinal: Constipation, dyspepsia, nausea, and vomiting

* **No** warnings/precautions of metabolic changes or tardive dyskinesia

Comparison to Other Antipsychotics

	First Generation Antipsychotics	Second Generation Antipsychotics	Cobenfy™
Mechanism of Action	Dopamine (D2) antagonism	Dopamine (D2) / Serotonin (5-HT_{2A}) antagonism	Muscarinic (M1/M4) agonism
Extrapyramidal Side Effects	More likely	Less likely	Unlikely
Metabolic Side Effects	Less likely	More likely	Unlikely
Generic Available?	Yes ($)	Most ($)	No ($$$)
Available Dosage Forms	● Oral ● Injectable	● Oral ● Injectable	● Oral only

References

Crismon, M. Lynn, et al. "Schizophrenia." *DiPiro's Pharmacotherapy: A Pathophysiologic Approach, 12th Edition* Eds. Joseph T. DiPiro, et al. McGraw Hill, 2023, https://accesspharmacy-mhmedical-com.www2.lib.ku.edu/content.aspx?bookid=3097&sectionid=267918845.

Cobenfy (xanomeline and trospium) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; September 2024.

POST-TEST

1. What is the FDA approved indication for use of Revumenib?

A. ER+, HER2- breast cancer
B. Advanced ovarian cancer
C. Acute relapsed or refractory leukemia caused by the translocation of the KMT2A gene
D. Acute relapsed or refractory Hodgkin lymphoma

POST-TEST

2. What is an advantage of using suzetrigine (Journavx)?

A. It is a well-established therapy and shows superiority to opioids
B. It may be used for chronic or acute pain
C. Although it is a controlled substance, it doesn't show signs of addiction
D. It is not an opioid or controlled substance, is generally well-tolerated, and useful for acute pain

THANK YOU!

Collect Your CE

The Lecture Panda code for this session is:

`{code here}`

All course credits from this conference must be submitted by Oct. 15, 2025.