


*Dependable outcomes in as few as* ***3 days***

## Dosing

**Can be taken with or without food**

**No dosage adjustments needed for patients with renal or hepatic impairment**

**1 tablet** (185 mg) orally

**3 times** per day

**for 3-7 days** clinically indicated[3]

**INDICATIONS AND USAGE**

**INDICATION**

Pivya is indicated for the treatment of female patients 18 years of age and older with uncomplicated urinary tract infections (uUTIs) caused by susceptible isolates of *Escherichia coli (E. coli), Proteus mirabilis,* and *Staphylococcus saprophyticus.*

**USAGE**

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Pivya and other antibacterial drugs, Pivya should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

- Serious hypersensitivity reactions (e.g., anaphylaxis or Stevens-Johnson syndrome) to Pivya or to other beta-lactam antibacterial drugs (e.g., penicillins and cephalosporins)
- Primary or secondary carnitine deficiency resulting from inherited disorders of mitochondrial fatty acid oxidation and carnitine metabolism, and other inborn errors of metabolism (e.g., methylmalonic aciduria, or propionic acidemia)
- Acute porphyria

**WARNINGS & PRECAUTIONS**

- Hypersensitivity reactions: Serious hypersensitivity reactions including anaphylaxis have been reported in patients treated with Pivya. If hypersensitivity reactions occur, discontinue treatment with Pivya and institute appropriate therapy.
- Severe Cutaneous Adverse Reactions (SCAR): Acute Generalized Exanthematous Pustulosis (AGEP), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Steven-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) have been reported with Pivya. Monitor patients closely and discontinue Pivya at the first signs or symptoms of SCAR or other signs of hypersensitivity.
- Carnitine Depletion: Clinically significant hypocarnitinemia has been observed in patients at risk for reductions in serum carnitine. In patients with significant renal impairment or decreased muscle mass and those patients requiring long term antimicrobial treatment, consider alternative antibacterial therapies. Pivya is not recommended when prolonged antibacterial treatment is necessary. Avoid concurrent treatment with valproic acid, valproate or other pivalate-generating drugs due to increased risk of carnitine depletion.
- *Clostridioides difficile*–associated diarrhea (CDAD): This has been reported for nearly all systemic antibacterial agents, including Pivya. Evaluate if diarrhea occurs.
- Interference with newborn screening test: Treatment of a pregnant individual with Pivya prior to delivery may cause a false positive test for isovaleric acidemia in the newborn as part of newborn screening. Prompt follow-up of a positive newborn screening result for isovaleric acidemia is recommended.
- The most common adverse reactions observed in ≥2% of the patients receiving Pivya in clinical trials are nausea and diarrhea.

Please see full Prescribing Information.
https://pivya.com/assets/pdf/pivya-prescribing-information.pdf?1

# *Help* ***your patients*** *save on* ***their Pivya prescription***




**The Pivya Savings Card helps eligible patients with commercial insurance reduce their out-of-pocket costs***

*This offer is valid for patients with commercial (private) insurance. It is not valid for patients enrolled in government-funded healthcare programs, such as Medicare, Medicaid, or TRICARE. Other restrictions may apply.
**Please see full terms and conditions.**
**https://pivya.com/saving-card.aspx**

## *How* ***your patient*** *can save on their Pivya prescription*

1. Ask your health care provider for a savings card or visit: www.pivya.com/saving-card.aspx
2. Present the card at the pharmacy
3. Receive savings on Pivya

**References**
1. Lodise TP, Kaye KS, Santerre Henriksen A, Kahlmeter G. Review of the in vitro microbiological activity of mecillinam against common uropathogens in uncomplicated urinary tract infection: focus on resistant pathogens. *Open Forum Infect Dis.* 2024;11(6):ofae296. 2. Gupta K, Trautner BW. Diagnosis and management of recurrent urinary tract infections in non-pregnant women. *BMJ.* 2013;346:f3140 . 3. Pivya. Prescribing information. Alembic Therapeutics; 2024. 4. Data on file.

# Pivya 185 mg

## Pivmecillinam tablets

For the treatment of uncomplicated urinary tract infections (uUTIs)



# ***Confidence when first-line matters***

*Targeted activity against the pathogens responsible for most uncomplicated UTIs*

Learn more at pivya.com

Alembic Therapeutics

# 1 in 5 patients with uUTI

receive ineffective empiric therapy

**UTIs are the most common bacterial infections and pose a significant burden to women**[1,2]

**The proportion of uUTIs caused by antibiotic-resistant bacteria is growing.**[1] Fluoroquinolone (FQ) and trimethoprim-sulfamethoxazole (TMP-SMX) resistance rates among *Escherichia coli*, the most common pathogen that causes UTIs, have exceeded 20% in most US regions[1]

## *Pivya* offers a **reliable option** in an **unpredictable resistance landscape**

**A targeted-spectrum antibiotic** active against *Escherichia coli, Proteus mirabilis,* and *Staphylococcus saprophyticus*[3]

**Highly specific inhibitory action** of PBP-2, resulting in low cross-resistance with certain β-lactams[3]

Despite nearly **50 years of clinical use in Europe** and **>30 million patients** treated worldwide, reported **resistance rates remain low** (4-6%)[1,4]



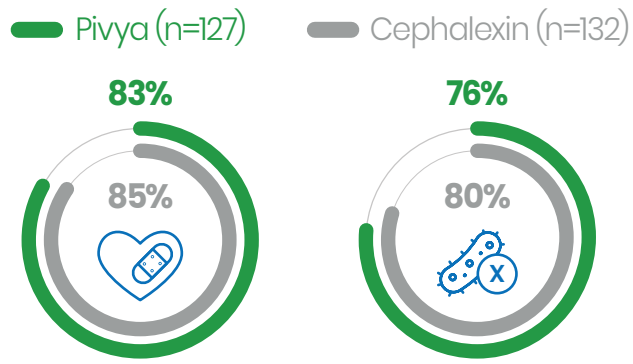
*A reliable first-line option with* ***proven outcomes*** *across clinical trials*

## *Pivya* has **demonstrated efficacy**

**Multi-center,** randomized, double-blinded study in the United States*

**Females ≥18 years** of age with uUTI[3]

**Pivya tablets 185 mg 3 times a day for 3 days** compared with cephalexin 250 mg 4 times a day for 7 days[3]




*Study investigated the clinical cure rate and the bacterial cure rate.
†Clinical cure was defined as no persisting symptoms during and post-therapy.
‡Microbiological response was defined as negative urine culture (<$10^3$ colony forming units/mL) for the initial pathogen at day 10.

## *with* **low rates** *of* **gastrointestinal adverse reactions**

**Zero** **serious adverse reactions** were reported in patients treated with **Pivya** in clinical trials[3]

**The most common adverse reactions** reported with **Pivya** occurred at low rates, with **nausea** reported at an incidence of **≤4.3%** **across 3 clinical trials**[3]

## **Reliable first-line treatment** *without unnecessary broad-spectrum exposure*



***Reliability*** *you can* ***start*** *and* ***end*** *with*

### Leah | 19 years old

Not actual patient, for illustrative purposes only

***MEDICAL HISTORY***
**No significant medical history**

**PRESENTING SYMPTOMS**
Dysuria, urinary frequency, urinary

**URINARY DIPSTICK POSITIVES**
Leukocytes, blood

**URINE CULTURE**
*Staphylococcus saprophyticus*

**DIAGNOSIS**
uUTI

**ANTIBIOTIC HISTORY**
Has not received antibiotics for UTIs

**CONSIDERATIONS**
A short-course, targeted-spectrum treatment may be appropriate for this otherwise healthy young woman with uUTI



***Reliability matters*** *more when resistance risk increases*

### Sarah | 36 years old

Not actual patient, for illustrative purposes only

***MEDICAL HISTORY***
**Recurrent UTIs**

**PRESENTING SYMPTOMS**
Dysuria, urinary frequency, urinary urgency,

**URINARY DIPSTICK POSITIVES**
Leukocytes, blood, protein

**URINE CULTURE**
*Escherichia coli* resistant to SMX and FQ

**DIAGNOSIS**
uUTI

**ANTIBIOTIC HISTORY**
uUTIs have been previously treated with amoxicillin, nitrofurantoin, and most recently (~1 month ago) with TMP-SMX

**CONSIDERATIONS**
Recent antibiotic exposure and recurrent UTI may raise concerns regarding antimicrobial resistance and prompt consideration of an agent with a distinct mechanism of action