

AMBER 1 GUIDANCE FOR PRESCRIBING OF PIVMECILLINAM

1. Background

Pivmecillinam is an antibiotic belonging to the penicillins class of antibacterials.

It has significant activity against many Gram-negative bacteria including E coli, klebsiella, enterobacter, and salmonellae. It is not active against Ps aeruginosa or enterococci.

2. Indication

Pivmecillinam is licensed in adults and children for the treatment of mecillinam sensitive organisms, including urinary tract infections and salmonellosis

In Hull, East Yorkshire, North Lincolnshire and North East Lincolnshire areas pivmecillinam is a RESTRICTED antibiotic. Use should be reserved for:

- the treatment of recurrent/resistant UTI in adults and children > 40kg with a limited number of treatment options AND either
- As directed in local antimicrobial guidance OR
- Prescribed by or recommended by a Consultant Microbiologist or Consultant in Infectious Disease including when recommended via culture results

Dose/Duration

Uncomplicated Lower Urinary Tract Infection

400mg STAT followed by 200mg 8hrly

(To complete 3 days in WOMEN, 7 days in MEN)

Recurrent Lower Urinary Tract Infections

Dose and duration as **advised by specialist** - may be long term

Usual dose is 400 mg (TWO tablets) three times daily.

In patients with severe renal impairment accumulation can occur. Dose reduction may be advised for long term use.

3. Contraindications/cautions

Avoid use in patients with hypersensitivity to the drug substance or any of the other ingredients; hypersensitivity to penicillins and/or cephalosporins; oesophageal strictures and/or obstructive changes in the gastrointestinal tract; a predisposition to carnitine deficiency; porphyria; pregnancy.

May be used during breast-feeding and no effects on the infant are anticipated. However, as for other penicillins, trace quantities of mecillinam is excreted into breast milk with the possible risk of sensitisation and subsequent allergic reactions in a sensitised infant.

5. Adverse effects

The most frequently reported adverse effects are gastrointestinal disorders such as nausea, vomiting and diarrhoea. Other reported adverse effects include dizziness, headache, urticarial rash, mouth ulcers and oesophagitis. There is also a risk of reduced serum and total body carnitine especially with long term or repeated use

6. Drug interactions

The following drugs are known or suspected interactions:	
Interacting Drug	Advice
Sodium valproate and valproic acid	Avoid use - increased risk of carnitine depletion
Methotrexate	Use in caution - possible rise of methotrexate levels. Consider withholding methotrexate in active infection
Probenecid	Use in caution - possible rise in pivmecillinam levels

7. Pregnancy and Lactation

Generally, penicillins as a class have not shown any increased risk of congenital malformations, miscarriage, intrauterine death, low birth weight, preterm delivery or neonatal complications following maternal exposure. However, the data with pivmecillinam is limited patient numbers and risk and benefit should be discussed with patient prior to treatment.

May be used during breast-feeding and no effects on the infant are anticipated. However, as for other penicillins, trace quantities of mecillinam is excreted into breast milk with the possible risk of sensitisation and subsequent allergic reactions in a sensitised infant.

8. Monitoring

If long term use, the following monitoring is recommended prior to initiation, then every month initially, reduced to 2-3 monthly on specialist advice

- Monitor Creatinine (U&Es) and Liver Function Tests

9. Information for patient

- Patients should be informed of risks and benefits of treatment.
- The tablets must be taken with at least half a glass of water, and preferably taken with or immediately after a meal

10. Contact details

Hull University Teaching Hospitals Trust. 01482 875875.

Ask for Infection consultant on call (may be a microbiologist or infectious disease consultant)

York Teaching Hospitals Foundation Trust. 01904 725856.

Ask for Microbiologist on call.

NLAG Foundation Trust. 03033 306999.

For results, extension 306610. For advice extension 306999

Document and version control	This information is not inclusive of all prescribing information and potential adverse effects. Please refer to the SPC (data sheet) or BNF for further prescribing information.		
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