

EmcilTM

Pivmecillinam HCl

COMPOSITION

EmcilTM Tablet: Each film coated tablet contains Pivmecillinam HCl BP 200 mg.

PHARMACOLOGY

Pivmecillinam belongs to a new class of Penicillin-the amdinopenicillin. Pivmecillinam is a prodrug formulation of mecillinam which allows the drug to be administered by mouth. The prodrug form lacks antibacterial activity, but the active drug is liberated by enzymatic hydrolysis during absorption in the gastrointestinal tract.

Pivmecillinam is bactericidal. It acts by interfering with bacterial cell wall synthesis, but the site of action differs from that of other penicillins. Pivmecillinam is very active against *Enterobacteriaceae*. It is active against *E. coli*, *Klebsiella*, *Proteus*, *Enterobacter*, *Salmonella*, *Shigella* and *Yersinia*. Pivmecillinam has poor activity against Gram-positive organisms. It has poor activity against *Pseudomonas aeruginosa* and has practically no activity against *Enterococcus faecalis*.

INDICATION

Pivmecillinam is indicated for treatment of infections caused by mecillinam-sensitive organisms, e.g., acute cystitis, complicated urinary tract infections, salmonellosis, shigellosis, enteropathic *E. coli* diarrhoea, gram-negative septicaemia, biliary infections.

DOSAGE AND ADMINISTRATION

Adults: The usual dose is 1-2 tablets 3 times daily according to severity of the infection. In acute uncomplicated cystitis, initially 400 mg, then 200 mg, every 8 hours for 3 days. In chronic or recurrent bacteriurea, 400 mg every 6-8 hours. For the treatment of salmonellosis (including enteric fever) a dose of 1.2-2.4 gm daily for 14 days. To eliminate salmonella carriage, therapy may be prolonged for 2-4 weeks. In complicated urinary tract infection the usual treatment time is 1-2 weeks. For prophylactic treatment of recurrent urinary tract infections 1 tablet every evening is recommended.

Children: Weighing less than 20 kg should be given 20-60 mg/kg divided into 3-4 daily doses. Those weighing more than 20 kg should receive normal adult dose. In shigellosis the dose is 20 mg/kg 4 times a day for 5 days. For UTI, 20-40 mg/kg/day in 3-4 divided doses. For salmonellosis, 30-60 mg/kg/day in 3-4 divided doses for 5 days.

The tablet should be taken with at least 50-100 ml fluid. As the bioavailability is practically unaffected by simultaneous food intake **EmcilTM** tablets are best taken with or immediately after a meal.

Patients with renal impairment:

Based on information available to date for patients with impaired renal function, the initial dose can remain unchanged as can the interval between doses. However, the amount administered as the maintenance dose should be changed according to the following criteria:

Creatinine clearance

30 ml/min or greater
10-30 ml/min
<10ml/min

Dosage

Full dosage
50% of full dosage
25% of full dosage

CONTRAINDICATION

There have been no reports on allergy to Pivmecillinam among patients with a known history of hypersensitivity to penicillins and cephalosporins. Nevertheless, it seems reasonable to exclude such patients from treatment with Pivmecillinam until further experience has been gained.

PRECAUTION

As with other antibiotics, which are excreted mainly by the kidneys, raised blood levels of mecillinam may occur if repeated doses are given with impaired renal function.

USE IN PREGNANCY AND LACTATION

Mecillinam concentrations approximately 1/3 of the serum levels have been found in the umbilical cord, and low but detectable amounts in the amniotic fluid. Data on a large number of exposed pregnancies indicate no adverse effects on pregnancy or on the foetus/new-born child. Pivmecillinam should only be prescribed when the expected benefits are considered to be greater than the potential risk. Mecillinam is not excreted into the milk of lactating mother.

USE IN CHILDREN

Use of Pivmecillinam in infants under 3 months of age should be avoided.

SIDE EFFECT

Pivmecillinam is generally well tolerated, even by patients with reduced kidney function. Upper gastrointestinal disturbances such as nausea, vomiting and diarrhoea or indigestion may occur when a dose has been given on an empty stomach. Skin rashes have been reported in some cases, but the characteristic ampicillin-rash has never been observed, nor has there been any evidence of hepato-, nephro-, or ototoxicity. The occurrence of anaphylaxis, though not yet reported, cannot be entirely excluded.

STORAGE

Store below 25°C. Protect from light & moisture. Keep out of reach of children.

PACKAGING

EmcilTM Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Manufactured by



TM - Trade Mark.