COMPOSITION: Emcil®: 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.

INDICATIONS: 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, billiary 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 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

The tablet should be taken with at least 50-100 ml fluid. As the bioavailability is practically unaffected by simultaneous food intake, Emcil ® 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 Dosage reduction
  30 ml/min or greater full dosage
  between 10-30 ml/min 50% dosage
  less than 10 ml/min 25% dosage
CONTRAINDICATIONS: 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.

PRECAUTIONS: 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.

PREGNANCY: 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. So, use of pivmecillinam in pregnancy should be avoided. 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 EFFECTS: 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.

OVER DOSAGE: There is no experience with over dosage of pivmecillinam. However, excessive doses are likely to cause nausea, vomiting and gastritis. Treatment should be restricted to symptomatic and supportive measures. If necessary haemodialysis will reduce the blood level.

PHARMACEUTICAL PRECAUTION: Store at a cool and dry place, protect from light and moisture.

PACKAGING: Box containing 5 x 6 film coated tablets in Alu-Alu blister pack.