

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

PYXIME

Cefixime Capsules 400 mg

COMPOSITION :

Each hard gelatin capsule contains :
Cefixime BP (As Trihydrate)
Eq. to Anhydrous Cefixime 400 mg
Excipients q.s.
Approved colors used in hard gelatin capsule shell

PHARMACOLOGICAL CLASSIFICATION:

Category A20.1.1. - Antimicrobial agents - Broad and Medium Spectrum Antibiotics.

PHARMACOLOGICAL ACTION:

PYXIME is an orally active cephalosporin antibiotic which has in-vitro bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms including Streptococcus pneumoniae, Streptococcus pyogenes, Escherichia coli, Proteus mirabilis, Klebsiella species, Haemophilus influenzae (beta-lactamase positive and negative), Moraxella (Branhamella) catarrhalis (beta-lactamase positive and negative). PYXIME is stable in the presence of beta-lactamase enzymes.

Most strains of enterococci (Streptococcus faecalis, group D. Streptococci) and staphylococci (including coagulase positive and negative strains and methicillin resistant strains) are resistant to PYXIME. In addition, most strains of Enterobacter and Pseudomonas, Bacteroides fragilis, Listeria monocytogenes and Clostridia are resistant to PYXIME.

INDICATIONS:

PYXIME is indicated for the treatment of the following infections when caused by susceptible micro-organisms.

Upper Respiratory Tract Infections; e.g., bacterial pharyngitis, tonsillitis, otitis media, sinusitis.

Lower Respiratory Tract Infections; e.g., bronchitis.

Urinary Tract Infections; e.g., acute cystitis.

Uncomplicated gonorrhoea.

CONTRA-INDICATIONS:

Allergy to cephalosporins.

PYXIME is contra-indicated in patients with renal impairment with a creatinine clearance below 60 mL/min.

WARNINGS:

PYXIME should be given with caution to patients who have shown hyper-sensitivity to other medicines. Cephalosporins should be given with caution to penicillin-sensitive patients as there is some evidence of partial cross-allergenicity between the penicillins and the cephalosporins. Patients have had severe reactions (including anaphylaxis) to both classes of drugs. If an allergic effect occurs with PYXIME the drug should be discontinued and the patient treated with appropriate agents if necessary.

PYXIME should be administered with caution in patients with markedly impaired renal function (See "Dosage in Renal Impairment").

Prolonged use of PYXIME may result in the overgrowth of non-susceptible organisms. PYXIME has been shown to alter the normal flora of the colon and may permit overgrowth of Clostridia. Studies indicate a toxin(s) produced by Clostridium difficile is the primary cause of antibiotic associated pseudomembranous colitis. The product should be discontinued if diarrhoea occurs.

DOSAGE AND DIRECTIONS FOR USE:

As directed by the Physician or as stated below :

Adults and Children over 12 Years:

The recommended adult dosage is 200 - 400 mg daily given either as a single dose or in two divided doses.

In lower respiratory tract infections, 400 mg daily is recommended.

For upper respiratory tract infections and uncomplicated urinary tract infections, 200 mg once daily is usually effective.

For sinusitis the therapeutic dosage must be administered for 10 to 14 days.

Treatment of uncomplicated Gonorrhoea: The recommended dosage is 400 mg as a single oral dose.

The Elderly:

Elderly patients may be given the same dose as recommended for adults. Renal function should be assessed and dosage should be adjusted in severe renal impairment.

Dosage in Renal Impairment: PYXIME may be administered in the presence of impaired renal function.

Normal dose and schedule may be given in patients with creatinine clearance of 20 mL/min or greater.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Precautions: Use in Pregnancy and Breast Feeding: Safe use in human pregnancy has not been established and it is not known whether PYXIME is excreted in human breast milk.

Side Effects:

Gastrointestinal Disturbances: The most frequent side effects seen with PYXIME are diarrhoea and stool changes. Moderate to severe diarrhoea has been reported. Other gastrointestinal side effects seen less frequently are nausea, abdominal pain, dyspepsia, vomiting and flatulence. Pseudomembranous colitis has been reported.

STORAGE INSTRUCTIONS:

Store below 30°C. Protect from light and moisture.

KEEP MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION :

6 Capsules

Marketed by:



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