Murex®
capsules

Cefixime

DESCRIPTION:
Murex® (cefixime) is an oral third generation cephalosporin which has a marked *in vitro* bactericidal activity against a wide variety of gram-positive and gram-negative organisms.
Inactive Ingredients: Sodium starch glycolate, pregelatinized starch, magnesium stearate.

PHARMACOLOGY:
Pharmacodynamics
Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens including *Streptococcus pneumoniae, Streptococcus pyogenes, Escherichia coli, Proteus mirabilis, Klebsiella species, Haemophilus influenzae* (beta-lactamase positive and negative), *Branhamella catarrhalis* (beta-lactamase positive and negative) and Enterobacter species. It is highly 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 cefixime. In addition, most strains of *Pseudomonas, Bacteroides fragilis, Listeria monocytogenes* and *Clostridia* are resistant to cefixime.
Pharmacokinetics
The absolute oral bioavailability of cefixime is in the range of 22-54%. Absorption is not significantly modified by the presence of food. Cefixime may therefore be given without regard to meals.
Serum or urine concentrations of 1 mcg/ml or greater are considered to be adequate for most common pathogens against which cefixime is active. Typically, the peak serum levels following the recommended adult or paediatric doses are between 1.5 and 3 mcg/ml. Little or no accumulation of cefixime occurs following multiple dosing.
The pharmacokinetics of cefixime in healthy elderly (age> 64 years) and young volunteers (11-35) compared the administration of 400 mg doses once daily for 5 days. Mean Cmax and AUC values were slightly greater in the elderly. Elderly patients may be given the same dose as the general population.
Cefixime is predominantly eliminated as unchanged drug in the urine. Glomerular filtration is considered the predominant mechanism. Metabolites of cefixime have not been isolated from human serum or urine.
Serum protein binding is well characterised for human and animal sera; cefixime is almost exclusively bound to the albumin fraction, the mean free fraction being approximately 30%. Protein binding of cefixime is only concentration dependent in human serum at very high concentrations which are not seen following clinical dosing.

INDICATIONS:
Murex® is an orally active cephalosporin antibiotic which has marked *in vitro* bactericidal activity against a wide variety of gram-positive and gram-negative organisms.
Murex® is indicated for the treatment of the following acute infections when caused by susceptible micro-organisms:
- Upper Respiratory Tract Infections (URTI): e.g. otitis media; and other URTI where the causative organism is known or suspected to be resistant to other commonly used antibiotics, or where treatment failure may carry significant risk.
- Lower Respiratory Tract Infection: e.g. bronchitis.
- Urinary Tract Infections: e.g. cystitis, cystourethritis, uncomplicated pyelonephritis.

CONTRAINDICATIONS:
Murex® is contraindicated in patients with known hypersensitivity to cephalosporin antibiotics.

SIDE EFFECTS:
Cefixime is generally well tolerated. The majority of adverse reactions observed were mild and self-limiting in nature.
Gastrointestinal Disturbances: The most frequent side effects seen with cefixime are diarrhoea and stool changes; diarrhoea has been more commonly associated with higher doses. Some cases of moderate to severe diarrhoea have been reported; this has occasionally warranted cessation of therapy. Cefixime should be discontinued if marked diarrhoea occurs. Other gastrointestinal side effects seen less frequently are nausea, abdominal pain, dyspepsia, vomiting and flatulence. Pseudomembranous colitis has been reported.
Central Nervous System: Headache and dizziness
Hypersensitivity Reactions: Allergies in the form of rash, pruritus, drug fever and arthralgia have been observed, including rare cases of urticaria or angioedema. These reactions usually subsided upon discontinuation of therapy. Rarely, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported.
Haematological and Clinical Chemistry: Thrombocytosis, thrombocytopenia, leucopenia, hypereosinophilia, neutropenia and agranulocytosis have been reported. These reactions were infrequent and reversible. Mild transient changes in liver and renal function tests have been observed.
Hepatic Disorders: Transient rises in liver transaminases, alkaline phosphatase and jaundice can also occur.
Miscellaneous: Other possible reactions include genital pruritus and vaginitis.

WARNINGS AND PRECAUTIONS:
- Cefixime should be given with caution to patients who have shown hypersensitivity to other drugs. Cephalosporins should be given with caution to penicillin-sensitive patients, as there is some evidence of partial cross-allergenicity between the penicillins and cephalosporins.
  Patients have had severe reactions (including anaphylaxis) to both classes of drugs. If an allergic effect occurs with cefixime, the drug should be discontinued and the patient treated with appropriate agents if necessary.
- Cefixime should be administered with caution in patients with markedly impaired renal function.
- Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of antibiotic-associated diarrhoea. Pseudomembranous colitis is associated with the use of broad-spectrum antibiotics (including macrolides, semi-synthetic penicillins, lincosamides and cephalosporins); it is therefore important to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Symptoms of pseudomembranous colitis may occur during or after antibiotic treatment.
- Management of pseudomembranous colitis should include sigmoidoscopy, appropriate bacteriologic studies, fluids, electrolytes and protein supplementation. If the colitis does not improve after the drug has been discontinued, or if the symptoms are severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by C. difficile. Other causes of colitis should be excluded.

Pregnancy and lactation:
There are no adequate and well-controlled studies in pregnant women. Cefixime should therefore not be used in pregnancy or in nursing mothers unless considered essential by the physician.

DRUG INTERACTIONS:
- A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.
- A false positive direct coomb's test has been reported during treatment with cephalosporin antibiotics, therefore it should be recognised that a positive coomb's test may be due to the drug.
- In common with other cephalosporins, increases in prothrombin times have been noted in a few patients. Care should therefore be taken in patients receiving anticoagulation therapy.

DOSAGE AND ADMINISTRATION:
Absorption of cefixime is not significantly modified by the presence of food. The usual course of treatment is 7 days. This may be continued for up to 14 days if required.
Adults and children over 10 years: The recommended adult dosage is 200-400 mg daily according to the severity of infection, given either as a single dose or in two divided doses.
Children weighing more than 50 kg or older than 10 years should be treated with the recommended adult dose (200 - 400 mg daily depending on the severity of infection). The safety and efficacy of cefixime have not been established in children less than 6 months.
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: Cefixime may be administered in the presence of impaired renal function. Normal dose and schedule may be given in patients with creatinine clearances of 20 ml/min or greater. In patients whose creatinine clearance is less than 20 ml/min, it is recommended that a dose of 200 mg once daily should not be exceeded. The dose and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis or haemodialysis should follow the same recommendation as that for patients with creatinine clearances of less than 20 ml/min.

OVERDOSAGE:
There is no experience with overdoses with cefixime.
Adverse reactions seen at dose levels up to 2 g cefixime in normal subjects did not differ from the profile seen in patients treated at the recommended doses. Gastric lavage may be indicated in overdosage. No specific antidote exists. Cefixime is not removed from the circulation in significant quantities by dialysis.

PRESENTATIONS:
Murex® 200 Capsules: Packs of 8 and 400 Capsules. Each capsule contains 200 mg cefixime (as cefixime trihydrate).
Murex® 400 Capsules: Packs of 5 and 500 Capsules. Each capsule contains 400 mg cefixime (as cefixime trihydrate).

STORAGE CONDITIONS:
Store below 30°C.

This is a medicament
Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold you the medicament.
The doctor and the pharmacist are experts in medicine, its benefits and its risks.
Do not, by yourself, interrupt the period of treatment prescribed.
Do not repeat the same prescription without consulting your doctor.

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Keep medicament out of reach of children | Manufactured by Dar Al Dawa, Na'ur - Jordan

دار الدواء
Dar Al Dawa

Murex® Insert | AE

Color
Pantone Black U
Size: 140X300 mm
Item Code: 4141567600
Pharma Code: 628