Maxpan

(Cefixime)

Description:
Maxpan (Cefixime) is a semi synthetic, antibiotic for oral administration.
Maxpan is available in 200mg & 400mg capsules and in powder form for oral suspension which when reconstituted provides100mg/5ml and 200mg/5ml.

Clinical Pharmacology:
Maxpan (Cefixime) given orally, is about 40%-50% absorbed whether administered with or without food, however, time to maximal absorption is increased approximately 0.8 hours when administered with food. Peak serum concentrations occur between 2 to 6 hours following of a single 400mg capsule or 400mg of suspension of cefixime.
Peak serum concentrations occur between 2 to 5 hours following a single administration of 200mg of suspension. Approximately 50% of the absorbed drug is excreted unchanged in the urine within 24 hours. In animal studies, it was noted that cefixime is also excreted in the bile in excess of 10% of the administered dose. Serum protein binding is concentration independent with a bound fraction of approximately 65%.
In subjects with moderate impairment of renal function (20 to 40ml/min creatinine clearance), the average serum half-life of cefixime is prolonged to 6.4 hours. In severe renal impairment (5 to 20ml/min creatinine clearance), the half-life is increased to an average of 11.5 hours. The drug is not cleared significantly from the blood by hemodialysis or peritoneal dialysis. However, a study indicated that with doses of 400 mg, patients undergoing hemodialysis have similar blood profiles as subjects with creatinine clearances of 21-60 ml/min. There is no evidence of metabolism of cefixime in vivo.
Adequate data on CSF levels of cefixime are not available.

Microbiology:
As with other cephalosporins, bactericidal action of cefixime results from inhibition of cell-wall synthesis. Cefixime is highly stable in the presence of beta-lactamase enzymes. As a result, many organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamases, may be susceptible to cefixime. Cefixime has been shown to be active against most strains of the following organisms both in vitro and in clinical infections.

Susceptibility of pathogens are as follows:
Gram-positive organisms.
Streptococcus pneumoniae, Streptococcus pyogenes,
Gram-negative Organisms.
Haemophilus influenzae (beta-lactamase positive and negative strains),
Moraxella (Branhamella) catarrhalis (most of which are beta-lactamase positive),
Escherichia coli, Proteus mirabilis,
Neisseria gonorrhoeae (including penicillinase- and nonpenicillinase-producing strains).
Cefixime has been shown to be active in vitro against most strains of the following organisms; however, clinical efficacy has not been established.
Gram-positive Organisms.
Streptococcus agalactiae.
Gram-negative Organisms.
Haemophilus parainfluenzae (beta-lactamase positive and negative strains),
Proteus vulgaris,
Klebsiella pneumoniae,
Klebsiella oxytoca,
Pasteurella multocida,
Providencia species,
Salmonella species,
Shigella species,
Citrobacter amalonaticus,
Citrobacter diversus,
Serratia marcescens.

Note:
Pseudomonas species, strains of group D streptococci (including enterococci), Listeria monocytogenes, most strains of staphylococci (including methicillin-resistant strains) and most strains of Enterobacter are resistant to cefixime. In addition, most strains of Bacteroides fragilis and Clostridia are resistant to cefixime.

Indications and Usage:
Maxpan (Cefixime) is indicated for the treatment of following infections when caused by susceptible strains of the designated microorganisms:
Uncomplicated Urinary Tract Infections caused by Escherichia coli and Proteus mirabilis.
Otitis Media caused by Haemophilus influenzae (beta-lactamase positive and negative strains), Moraxella (Branhamella) catarrhalis, (most of which are beta-lactamase positive) and S. pyogenes.
Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis, caused by Streptococcus pneumoniae and Haemophilus influenzae (beta-lactamase positive and negative strains).

Uncomplicated gonorrhoea (cervical/urethral), caused by Neisseria gonorrhoeae (penicillinase- and non-penicillinase-producing strains).
Appropriate cultures and susceptibility studies should be performed to determine the causative organism and its susceptibility to cefixime however, therapy may be started while awaiting the results of these studies.
Therapy should be adjusted, if necessary, once these results are known.
Maxpan (Cefixime) may be used as empiric treatment for susceptible microorganism but when culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Dosage and Administration:
Adults:
The recommended dose of cefixime is 400mg daily. This may be given as a 400mg capsule daily or as 200mg capsule every 12 hours. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400mg is recommended.

Children:
The recommended dosage is 8mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4mg/kg every 12 hours.
Children weighing more than 50kg or older than 12 years should be treated with the recommended adult dose. Efficacy and safety in infants aged less than six months have not been established.
For the treatment of infections due to S.pyogenes, a therapeutic dosage of Maxpan should be administered for at least 10 days.

Renal Impairment:
Maxpan may be administered in the presence of impaired renal function. Normal dose and schedule may be employed in patients with creatinine clearance of 60ml/min or greater. Patients whose clearance is between 21 and 60ml/min or patients who are on renal hemodialysis may be given 75% of the standard dosage at the standard dosing interval (i.e, 300mg daily). Patients whose clearance is <20ml/min, or patients who are on continuous ambulatory peritoneal dialysis may be given half the standard dosage at the standard dosing interval (i.e, 200mg daily). Neither hemodialysis nor peritoneal dialysis removes significant amounts of drug from the body.

Side Effects:
Most of adverse reactions observed in clinical trials were of a mild and transient nature. The most commonly seen adverse reactions were gastrointestinal events. Clinically mild gastrointestinal side effects occurred in 20% of all patients, moderate events occurred in 9% of all patients and severe adverse reactions occurred in 2% of all patients. Individual event rates included diarrhoea 16%, loose or frequent stools 6%, abdominal pain 3%, nausea 7%, dyspepsia 3%, and flatulence 4%. These symptoms usually responded to symptomatic therapy or caused when Cefixime was discontinued.
Several patients developed severe diarrhoea and/or documented pseudomembranous colitis, and a few required hospitalization.
The following adverse reactions have been reported following the use of Cefixime. Incidence rates were less

than 1 in 50 (less than 2%), except as noted above for gastrointestinal events.

Hypersensitivity Reactions:
Anaphylactic/anaphylactoid reactions (including shock and fatalities), rashes, urticaria, drug fever, pruritus, angioedema, and facial edema. Erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have been reported with cefixime.

Hepatic:
Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, jaundice.

Renal:
Transient elevations in BUN or creatinine, acute renal failure.

Central Nervous System:
Headaches, dizziness, seizures.

Hemic and Lymphatic Systems:
Transient thrombocytopenia, leukopenia, neutropenia, and eosinophilia. Prolongation in prothrombin time was seen rarely.

Abnormal Laboratory Tests:
Hyperbilirubinemia.

Other:
Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis.
In addition to the adverse reactions listed above which have been observed in patients treated with Cefixime, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics:

Adverse reactions:
Allergic reactions, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, anemia, hemorrhage, and colitis.

Drug Interactions:
Carbamazepine: Elevated levels have been reported in postmarketing experience when Cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.
Warfarin and Anticoagulants: Increased prothrombin time, with or without bleeding, has been reported when cefixime is administered concomitantly.

Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of Cefixime.

Precautions:
General:
The possibility of the emergence of resistant organisms which might result in overgrowth should be kept in mind, particularly during prolonged treatment. In such use, careful observation of the patient is essential. If super-infection occurs during therapy, appropriate measures should be taken.
The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Patients on dialysis should be monitored carefully.
Cefixime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
Cephalosporins may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin should be monitored in patients at risk exogenous and vitamin K administered as indicated.
Prescribing ***Maxpan*** (Cefixime) in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide to the patient and increases the risk of development of drug-resistant bacteria.

Usage in Pregnancy:
In the absence of adequate and well-controlled studies in pregnant woman, this drug use during pregnancy is not recommended unless or until benefits outweight the risks.

Labor and Delivery:
Maxpan (Cefixime) has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.

Nursing Mothers:
It is not known whether ***Maxpan*** (Cefixime) is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

Pediatric Use:
Safety and effectiveness of ***Maxpan*** (Cefixime) in children aged less than six months old have not been established. The incidence of gastrointestinal adverse reactions, including diarrhoea and loose stools, in the pediatric patients receiving the suspension, was comparable to the incidence seen in adult patients receiving capsules.

Overdose:
Gastric lavage may be indicated; otherwise, no specific antidote exists. ***Maxpan*** (Cefixime) is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in small numbers of healthy adult volunteers receiving single doses up to 2g of Cefixime did not differ from the profile seen in patients treated at the recommended doses.

Contraindications:
Maxpan is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Direction for Preparation:
Tap the bottle several times before reconstitution to loosen the powder contents.
The purified water provided with the pack should be added in two portions (total 20 ml) to prepare 30 ml of suspension.
Mix well after each addition until a uniform suspension is formed.

Storage:
See outer carton.

Availability:
- ***Maxpan* - 200** Capsule : 10 Capsules.
- ***Maxpan* - 400** Capsule : 5 Capsules.
- ***Maxpan* - 100** Oral Suspension 30ml after reconstitution.
- ***Maxpan* - 200** Oral Suspension 30ml after reconstitution.

Keep all medicines out of the reach of children.

Manufactured by :
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