

Winex®

Cefixime Capsules / Oral Suspension

Composition:

Winex 200: Each capsule contains Cefixime (as Trihydrate) 200mg.

Winex 400: Each capsule contains Cefixime (as Trihydrate) 400mg.

Excipients: Cellulose, sodium lauryl sulfate and magnesium stearate.

Winex Oral Suspension: Each 5ml contains Cefixime (as Trihydrate) 100mg.

Excipients: Sucrose, xanthan gum, flavour and sodium benzoate.

Properties:

Cefixime is a semisynthetic bactericidal third generation cephalosporin antibiotic. Its antibacterial activity results from the inhibition of mucopeptide synthesis in bacterial cell wall. It has high affinity for penicillin binding proteins. Cefixime has an expanded spectrum of activity against gram-negative bacteria compared with first and second generation cephalosporins. However it is not active against most strains of Enterobacter and Pseudomonas. 30 - 50% of a single dose of Cefixime is absorbed following oral administration, food decreases its rate of absorption. It reaches its peak serum concentration in a range of 2-6 hours. Cefixime is approximately 65 - 70% bound to serum proteins and its serum elimination half life is 2.4 - 4 hours. Serum half life is independent of dose and dosage form and is prolonged in patients with impaired renal function.

Indications:

Winex is used in the treatment of uncomplicated urinary tract infections caused by susceptible bacteria, acute otitis media, pharyngitis and tonsillitis caused by Streptococcus pyogens and respiratory tract infections such as acute and chronic bronchitis and pneumonia, and for the treatment of uncomplicated gonorrhoea.

Contraindications:

Winex is contraindicated for patients with known hypersensitivity to any of its components or to other cephalosporins or penicillins, porphyria.

Precautions:

Cefixime should be used in caution in patients with a history of GI disease particularly colitis, in patients with renal impairment and in nursing mothers.

Interactions with other drugs:

Concomitant administration of:

- Probenecid increases peak serum concentrations of Cefixime.
 - Salicylic acid increases free Cefixime by 50% due to displacement of Cefixime from protein binding sites, this effect is concentration-dependant.
 - Cefixime may increase plasma concentrations of Carbamazepine.
 - Nifedipine increases the bioavailability of Cefixime.
- Concomitant administration of Cefixime with furosemide, aminoglycosides may be possible additive to nephrotoxicity.

Warnings:

Avoid prolong use of Cefixime, because this may result in overgrowth of non-susceptible organisms.

Dosage and Administration:

The usual adult dose of Cefixime is 400mg daily, it can be given as a single daily dose or 200mg given every 12 hours.

For treatment of gonococcal infections, 400mg are given twice daily to complete 7 days of treatment.

For children 6 months to 12 years of age, 8mg/kg daily dose is recommended, it can be given as a single dose or 4mg/kg every 12 hours.

Dosage in renally impaired patients:

| Creatinine Clearance | Dose |
|----------------------|-----------------------------------|
| > 60 ml/min | No modification of the usual dose |
| 21 - 60 ml/min | 75% of the usual dose |
| < 20 ml/min | 50% of the usual dose |

Overdosage:

Symptoms of overdose include mild to moderate adverse GI effects. The stomach should be emptied by gastric lavage.

Side Effects:

GI effects: Diarrhea, loose frequent stools, abdominal pain, anorexia, nausea, vomiting, dyspepsia, flatulence, pruritus ani and dry mouth.

Nervous system effects: Headache, dizziness, nervousness, insomnia, somnolence, malaise and fatigue.

Sensitivity reactions: Rash, urticaria, drug fever, pruritus and arthralgia.

Hematologic effects: Transient thrombocytopenia, leukopenia, eosinophilia, and decreased hemoglobin concentration.

Consult your Pharmacist or Physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15-30 °C).

Winex oral suspension:

Keep at temperature below 25 °C.

Do not use beyond the expiry date or if the product shows any sign of deterioration.

Presentations:

Winex 200 : Packs of 8 capsules.

Winex 400 : Packs of 6 capsules.

Winex Oral suspension: Bottle of 30 ml.

Hospital packs are available.

® is a trademark.

THIS IS A MEDICAMENT

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

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.



Manufactured by:
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Sep.2002
24050/P2