

Important Information. Please read carefully.

Sofilex[®] 250mg

Capsules

Composition

Each capsule contains Cephalexin Monohydrate equivalent to Cephalexin 250 mg

Pharmacodynamics

Cephalexin is a beta-lactam antibiotic. It is bactericidal and acts by inhibiting synthesis of the bacterial cell wall. It has good activity against a wide spectrum of activity and is of low toxicity.

Pharmacokinetics

Cephalexin is almost completely absorbed from the gastro-intestinal tract. If Cephalexin is taken with food, absorption may be delayed, but the total amount absorbed is not appreciably altered. It crosses the placenta and small quantities are found in the milk of nursing mothers. Cephalexin is not metabolised. About 80% or more of a dose is excreted unchanged in the urine, some may be excreted in the bile.

Indications

Cephalexin is administered by mouth for the treatment of susceptible infections including those of the respiratory, urinary tracts and of the skin.

It is also indicated in upper respiratory infections including pharyngitis and tonsillitis (caused by *Streptococcus pyogenes*) and otitis media (caused by *Strep. Pneumoniae*, *H. Influenza*, *Staphylococci* and *S. pyogenes*).

Dosage and Administration

To be administered orally. The usual dose for adults is 1 to 2 g daily given in divided doses at 6-, 8-, or 12 hourly intervals; in severe or deep-seated infections the dose can be increased to up to 6 g daily. Children may be given 25 to 100 mg per kg body-weight daily in divided doses to a maximum of 4 g daily. Doses may need to be reduced in severe renal impairment. Renal and haematological status should be monitored especially during prolonged and high-dose therapy.

Contraindications

Hypersensitivity to Cephalosporins. Contraindicated in patients hypersensitive to Penicillins. Care in patients with known histories of allergy.

Precautions

Cephalexin should not be given to patients who are hypersensitive to it or to other Cephalosporins. About 10% of Penicillin sensitive patients may also be allergic to Cephalosporins although the true incidence is uncertain; great care should be taken if cephalexin is to be given to such patients. Care is also necessary in patients with known histories of allergy. Cephalexin should be given with caution to patients with renal impairment; a dosage reduction may be necessary. Cephalexin should be used with caution in patients with a history of GI disease, particularly colitis. Cephalexin is distributed into milk. It should be used with caution in nursing women. Prolonged use may result in overgrowth of non-susceptible organisms, especially *Enterobacter*, *Pseudomonas*, *Enterococci*, or *Candida*. If an allergic reaction to Cephalexin occurs, discontinue the drug and patient should be treated with the appropriate agents. Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Sofilex, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Sofilex must be discontinued immediately and appropriate alternative therapy instituted.

Drug Interactions

Cephalexin may interfere with method of measuring creatinine concentration, the direct Coombs' test and urine glucose test using copper-reduction reactions.

There may also be enhanced nephrotoxicity with concomitant use of nephrotoxic drug such as aminoglycoside and loop diuretic like frusemide. Probenecid delays urinary excretion of Cephalexin. There may be antagonism between Cephalexin and bacteriostatic antibacterial agents.

Incompatibilities

None known.

Usage during Pregnancy

As with all other drugs, it should be administered with caution during early months of pregnancy.

Overdosage and Treatment

Symptoms: Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhoea and hematuria. Treatment: Unless 5 to 10 times the normal dose of Cephalexin has been ingested, gastrointestinal decontamination should not be necessary. Protect the patient's airway and support ventilation and perfusion. To decrease gastrointestinal absorption of Cephalexin, charcoal can be considered instead of or in addition to gastric emptying. The benefits of forced diuresis, peritoneal dialysis, haemodialysis, or charcoal hemoperfusion in treating Cephalexin overdosage have not been established.

Side Effects

The most common adverse effects of Cephalexin and other oral Cephalosporins are generally gastrointestinal disturbances (including nausea, vomiting and diarrhoea) and hypersensitivity reactions (including skin rashes, urticaria, eosinophilia, fever, reactions resembling serum sickness and anaphylaxis). Pseudomembranous colitis has been reported.

Neutropenia, thrombocytopenia and agranulocytosis have occasionally been reported. Allergic reactions have been observed in the form of rash, urticaria, angioedema and rarely erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis. These reactions subsided upon discontinuation of the drug, although in some cases, supportive therapy may be necessary.

Presentation

Dark green & light green hard gelatin capsules in packs of 1000's. 10's in blister pack.

Shelf-Life

The expiry date is indicated on the packaging.

Storage

Keep container well closed. Protect from light. Store below 30°C.

KEEP OUT OF REACH OF CHILDREN.

JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

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Manufacturer and Product Registration Holder

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