



Cefalexin

Ceporex Oral Preparations

PRODUCT DESCRIPTION

Cefalexin (Ceporex) 500mg Capsules: Each capsule contains 500mg Cefalexin. The capsule is Size #0 hard gelatine capsule with an opaque caramel coloured body printed with GS 3ZI axially in white ink and a plain opaque dark grey cap containing white to yellowish white powder. *It contains Magnesium stearate as an excipient.*

Cefalexin (Ceporex) 125mg/5mL Powder for Suspension: *Each 5 ml of constituted suspension contains 125 mg of cefalexin. Excipients include Sodium calcium edetate, Acacia, Orange Bramble Flavour SO 370, Polvaromas, Citric Acid BP anhydrous 100-Mesh, Sodium citrate anhydrous, Sunset Yellow Ariavit, Caster sugar, Icing sugar. The powder prior to reconstitution has a pale pink coarse powder with characteristic odour.*

Cefalexin (Ceporex) 250mg/5mL Powder for Suspension: *Each 5 ml of constituted suspension contains 250 mg of cefalexin. Excipients include Sodium calcium edetate, Acacia, Orange Bramble Flavour SO 370, Polvaromas, Citric Acid BP anhydrous 100-Mesh, Sodium citrate anhydrous, Sunset Yellow Ariavit, Caster sugar, Icing sugar. The powder prior to reconstitution has a pale pink coarse powder with characteristic odour.*

Cefalexin (Ceporex) Powder for Suspension (Oral Drops): *Each 1 ml of constituted drops contains 100 mg of cefalexin. Excipients include Sodium calcium edetate, Acacia, Orange Bramble Flavour SO 370, Polvaromas, Citric Acid BP anhydrous 100-Mesh, Sodium citrate anhydrous, Sunset Yellow Ariavit, Caster sugar. The powder prior to reconstitution gives a pale pink to orange granules with a characteristic odour.*

PHARMACOLOGICAL PROPERTIES

Mechanism of Action

Cefalexin is an oral broad- spectrum antibiotic. In adequate concentrations it is bactericidal for sensitive proliferating microorganisms by inhibiting the biosynthesis of the cell wall.

Pharmacodynamics

It is active against the following pathogens:

Gram Positive

Staphylococci (coagulase positive as well as penicillinase- producing strains), *Streptococci*, *pneumococci*, *Corynebacterium diphtheriae*, *Bacillus anthracis*, *Clostridia*, *Listeria monocytogenes*, *Bacillus subtilis* and *Bacteroides melaninogenicus*.

Gram Negative

Escherichia coli, *Salmonellae*, *Shigellae*, *Neisseria*, *Proteus mirabilis*, *Haemophilus influenzae* (some strains), *Brucellae*, *Klebsiella species*, *Treponema pallidum* and *actinomycetes*.

Pharmacokinetics

Absorption

Cefalexin is almost completely absorbed from the gastrointestinal tract and produces peak plasma concentrations about 1 hour after administration.

A dose of 500 mg produces a peak plasma concentration of about 18 µg per mL; doubling the dose doubles the peak concentration.

Distribution

Cefalexin readily diffuses into tissues, including bone, joints, and the pericardial as well as pleural cavities. Only 10-15% of the dose is bound to plasma proteins.

Elimination

Elimination is mainly renal with 80% of the dose, recovered from the urine, therapeutically active, in the first 6 hours.

Cefalexin does not enter cerebrospinal fluid in significant quantities. Cefalexin crosses the placenta and small quantities are found in the milk of nursing mothers.

Therapeutically effective concentrations may be found in the bile and some may be excreted by this route.

The half- life has been reported to range from 0.5 to 2 hours and this increases with reduced renal function.

Pre-clinical Safety Data

Cefalexin is not anticipated to cause any genotoxic or carcinogenic effects, although no specific studies have been performed to determine this.

INDICATIONS

Cefalexin (Ceporex) is a bactericidal antibiotic which is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for treatment of the following conditions, when caused by susceptible bacteria. It is indicated for treatment of respiratory tract infections (RTIs), urinary tract infections (UTIs), skin and soft tissue infections, otitis media and other infections due to sensitive organisms.

DOSAGE AND ADMINISTRATION

Oral formulations

Each capsule should be swallowed whole with water.

Route of Administration

Oral formulations: For oral use.

Adults

The dosage is 1-4 g daily in divided doses. Most infections will respond to 500 mg every 8 hours. For skin and soft tissue infections, *streptococcal* pharyngitis and mild uncomplicated UTIs, the usual dosage is 250 mg every 6 hours or 500 mg every 12 hours. For more severe infections or those caused by less susceptible organisms, larger doses may be needed.

Children

The usual recommended daily dosage for children is 25-50 mg/kg in divided doses. For skin and soft tissue infections, *streptococcal* pharyngitis and mild, uncomplicated urinary tract infections, the total daily dose may be divided and administered every 12 hours. For most infections the following schedule is suggested:

Children under 5 years - 125 mg every 8 hours

Children 5 years and over - 250 mg every 8 hours

In severe infections the dosage may be doubled. In the therapy of otitis media, clinical studies have shown that a dosage of 75-100 mg/kg/day in 4 divided doses is required. In the treatment of beta- haemolytic *streptococcal* infections, a therapeutic dose should be administered for at least 10 days.

Elderly

The dosage is as for adults. The dosage should be reduced if renal function is markedly impaired.

Renal impairment

The dosage should be reduced if renal function is markedly impaired.

Hepatic impairment

There are no relevant data available.

CONTRAINDICATIONS

Cefalexin (*Ceporex*) is contraindicated in patients with known allergy to the cephalosporin group of antibiotics. Severe systemic infections, which require parenteral cephalosporin treatment, should not be treated orally during the acute stage.

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions

Cefalexin (*Ceporex*) should be given cautiously 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 drugs. If the patient experiences an allergic reaction cefalexin should be discontinued and treatment with the appropriate agents initiated.

Pseudomembranous colitis

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics, including macrolides, semisynthetic penicillins and cephalosporins. It is important, therefore, to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening. Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, appropriate measures should be taken.

Superinfection

Prolonged use of cefalexin may result in the overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Renal impairment

Cefalexin (*Ceporex*) should be administered with caution in presence of markedly impaired renal function as it is excreted mainly by the kidneys. Careful clinical and laboratory studies should be made because the safe dosage may be lower than the usually recommended (*see Dosage and Administration*).

Direct Coombs test

Positive direct Coombs' tests have been reported during treatment with cephalosporin antibiotics. For haematological studies, or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side, or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognised that a positive Coombs' test may be due to the drug.

False-positive glycosuria reaction

A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets. Tests based on glucose oxidation reactions may be safely used.

Sucrose

Cefalexin (*Ceporex*) 100 mg/mL Powder for Suspension (Oral Drops)

Cefalexin (*Ceporex*) 125 mg/5 mL Powder for Suspension

Cefalexin (*Ceporex*) 250 mg/5 mL Powder for Suspension

These products contain sucrose. Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this products.

Ability to perform tasks that require judgement, motor or cognitive skills

There are no effects on ability to drive or to operate machinery.

DRUG INTERACTIONS

Bacteriostatic antibiotics

As cephalosporins like cefalexin are only active against proliferating microorganisms, they should not be combined with bacteriostatic antibiotics.

Uricosuric drugs

Concomitant use of uricosuric drugs (e.g. probenecid) suppresses renal drug elimination. As a result, cefalexin plasma levels are increased and sustained for longer periods.

Metformin

A potential interaction between cefalexin and metformin may result in an accumulation of metformin and could result in fatal lactic acidosis.

Increased risk of nephrotoxicity

If associated with highly potent diuretics (ethacrynic acid, furosemide) or other potentially nephrotoxic antibiotics (aminoglycosides, polymyxin, colistin) cephalosporins may show higher nephrotoxicity.

Oral anticoagulants

Combined use of cephalosporins and oral anticoagulants may prolong prothrombin time.

Typhoid vaccine

Cefalexin (*Ceporex*), like other antibiotics with antibacterial activity against salmonella typhi organisms, may interfere with the immunological response to the live typhoid vaccine. The appropriate period of time should elapse between the administration of the last dose of the antibiotic and the live typhoid vaccine.

Oral contraceptives

Cefalexin (*Ceporex*) may reduce the effects of oral contraceptives.

Cytotoxic drugs

Hypokalaemia has been described in patients taking cytotoxic drugs for leukaemia when they were given gentamicin and cefalexin.

PREGNANCY AND LACTATION

Fertility: There are no relevant data available.

Pregnancy: There is no experimental or clinical evidence of teratogenic effects attributable to cefalexin, but Cefalexin (*Ceporex*) should be administered with caution during pregnancy.

Lactation: Cefalexin is excreted in human milk in low concentrations and should be used with caution in nursing mothers.

The excretion of cefalexin in human breast milk increased up to 4 hours following a 500mg dose. The drug reached a maximum level of 4 micrograms/ml, then decreased gradually and had disappeared 8 hours after administration.

ADVERSE EFFECTS

Side effects of Cefalexin (*Ceporex*) include gastro-intestinal disturbances such as nausea, vomiting, diarrhea and abdominal discomfort. The most common of these effects is diarrhea, but this is rarely severe enough to warrant cessation of therapy. Dyspepsia has also occurred.

Transient hepatitis and cholestatic jaundice have rarely been reported.

Allergic reactions have been reported such as rash, urticaria, angioedema and rarely erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis (exanthematic necrolysis). These reactions usually subsided upon discontinuation of the drug, although in some cases supportive therapy may be necessary. Anaphylaxis has also been reported.

Other side effects such as genital and anal pruritus, genital candidiasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis and joint disorders have been reported.

As with other cephalosporins interstitial nephritis has rarely been reported.

Eosinophilia, neutropenia, thrombocytopenia, haemolytic anaemia and slight elevations in AST and ALT have been reported.

As with other broad- spectrum antibiotics prolonged use may result in the overgrowth of non-susceptible organisms, e.g. candida. This may present a vulvo- vaginitis.

There is a possibility of development of pseudomembranous colitis and it is therefore important to consider its diagnosis in patients who develop diarrhea while taking cefalexin (*Ceporex*). It may range in severity from mild to life threatening with mild case usually responding to cessation of therapy. Appropriate measures should be taken with moderate to severe cases.

OVERDOSAGE AND TREATMENT

Overdosage

Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhea and haematuria.

Treatment

General management consists of close clinical and laboratory monitoring of haematological, renal and hepatic functions and coagulation status until the patient is stable. Serum levels of cefalexin can be reduced by haemodialysis or by peritoneal dialysis.

Unless 5 to 10 times the normal total daily dose has been ingested, gastro-intestinal decontamination should not be necessary.

There have been reports of haematuria without impairment of renal function in children accidentally ingesting more than 3.5g of cefalexin in a day. Treatment has been supportive (fluids) and no sequelae have been reported.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

Incompatibilities

No incompatibilities have been reported.

STORAGE CONDITIONS

Cefalexin (*Ceporex*) 500mg capsule: Store at temperatures not exceeding 25°C.

Cefalexin (*Ceporex*) 125mg/5mL Powder for Suspension: Store at temperatures not exceeding 25°C. Cefalexin

(*Ceporex*) 250mg/5mL Powder for Suspension: Store at temperatures not exceeding 25°C. Cefalexin (*Ceporex*)

100mg/mL Powder for Suspension (Oral Drops): Store at temperatures not exceeding 25°C.

The reconstituted suspension will retain its potency for 7 days when stored at temperatures not exceeding 25°C and 14 days when refrigerated (2 - 8°C).

INSTRUCTIONS FOR USE AND HANDLING

Suspensions

Cefalexin (*Ceporex*) suspensions are prepared by adding water to the powder to give suspensions containing 125, 250 mg Cefalexin (*Ceporex*) in each 5 mL.

Paediatric Drops

Slowly add 6 mL of water. Replace cap and shake well. Discard cap and fit dropper.

AVAILABILITY

Cefalexin (*Ceporex*) 500 mg Capsules: Alu-Alu foil strip x 10's (Box of 50's)
Cefalexin (*Ceporex*) 250 mg/5 mL Powder for Suspension: Amber Bottles of 30 and 70 mL.
Cefalexin (*Ceporex*) 125 mg/5 mL Powder for Suspension: Amber Bottles of 70 mL. Cefalexin (*Ceporex*) 100 mg/mL Powder for Suspension (Oral Drops): Amber Bottles of 10 mL.

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Keep all medicines out of reach of children.

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