Cepalexin

**Composition:** Cephalexin

Granules for oral suspension: when reconstituted each 5 ml contain 139.5 mg Cephalexin monohydrate equivalent to 125 mg Cephalxin or 279.5 mg Cephalexin monohydrate equivalent to 250 mg Cephalxin or Cephalexin monohydrate 553.23 mg equivalent to 500 mg cephalexin. **List of Excipients:** Film coated Tablet: Magnesium Stearate, Microcrystalline Cellulose, aqueous film coat. Granules for oral suspension: sodium calcium Edetate – Acacia powder- Citric acid anhydrous- Sodium citrate anhydrous- Sunset yellow- Orange-bramble flavour polvaromas- Sucrose powder- water. **Indications:** Cephalexin 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. It is indicated in dental infection with susceptible organisms. **Dosage and Administration:** Route of Administration: For oral use. Oral formulations: **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. For dental procedures and infections: 500 mg every 6 hours, 2 gm 1 hour pre-operative (joint prophylaxis). **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. **For Ceporex 500 mg/ 5 ml suspension:** The dose is 25-50 mg/kg/day in divided doses (8-12 hours). In severe infections, the dosage may be doubled. In the therapy of otitis media, clinical studies have shown that a dosage of 75-100mg/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. For dental procedures and infections: 25-50 mg/kg/day divided into 4 doses. **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:** Hypersensitivity to the active substance, to other cephalosporins or to any of the excipients. Previous immediate and/or severe hypersensitivity reaction to penicillin or to any other beta-lactam medicinal products. Severe systemic infections, which require parenteral cephalosporin treatment, should not be treated orally during the acute stage. **Warnings and Precautions:** Special caution is required to determine any other type of previous hypersensitivity reactions to penicillin or to other beta-lactam medicinal products because patients hypersensitive to these medicines may be hypersensitive to cephalexin as well (cross-allergy). **Hypersensitivity reactions:** Cefalexin 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. **Acute generalised exanthematous pustulosis (AGEP):** Acute generalised exanthematous pustulosis (AGEP) has been reported in association with cepalexin treatment. At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, cefalexin should be withdrawn immediately and an alternative treatment considered. Most of these reactions occurred most likely in the first week during treatment. **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 cephalexin 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: Cephalexin should be administered with caution in the 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 that usually recommended. 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.

Ceporex syrup 125 mg /5 ml granules for oral suspension, Ceporex syrup 250 mg /5 ml granules for oral suspension and Ceporex 500 mg /5 ml granules for oral suspension: Sucrose: These products contain sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this product. To be used with caution in patients with diabetes mellitus. Interactions: Bacteriostatic antibiotics: As cephalosporins like cephalaxin 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, cephalaxin plasma levels are increased and sustained for longer periods. Metformin: A potential interaction between cephalaxin 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 (ethacryninic 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: Cephalaxin, 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 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 cephalaxin. Pregnancy and Lactation: Fertility: There are no relevant data available. Pregnancy: It should be administered with caution during pregnancy. There is no experimental or clinical evidence of teratogenic effects attributable to cephalaxin. Lactation: Cephalexin is excreted in human milk in low concentrations and should be used with caution in nursing mothers. The excretion of cephalaxin 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. Ability to perform tasks that require judgement, motor or cognitive skills: There are no effects on ability to drive or to operate machinery. Adverse Reactions: Side effects of cephalexin include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea and abdominal discomfort. The most common of these effects is diarrhoea, 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, toxic epidermal necrolysis (exanthematic necrolysis) and acute generalised exanthematous pustulosis (AGEP) (with unknown frequency). 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 diarrhoea while taking cephalaxin. 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: Signs and Symptoms: Symptoms of oral overdose
may include nausea, vomiting, epigastric distress, diarrhoea 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 cephalexin 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 cephalexin in a day. Treatment has been supportive (fluids) and no sequelae have been reported. **Special Precautions for Storage:** For granules for oral suspension: to be stored at temperature not exceeding 30°C, after reconstitution it retains their potency for 7 days when stored at (2-8°C). The granules for oral suspension may be diluted with water (not Syrup BP), after which they should be used within seven days. **Full Prescribing Information is available on request. Please read the full prescribing information prior to administration.**