SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cefalexin 500 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Cefalexin monohydrate equivalent to 500mg Cefalexin.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablets
Round pink film coated tablets embossed ‘CHX 500’ on one side

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cefalexin is indicated in the treatment of the following infections: Respiratory tract infections; bone and joint infections; genito-urinary infections, including acute prostatitis and dental infections.
Cefalexin is active against the following organisms: Beta-haemolytic streptococci; staphylococci, including coagulasepositive, coagulase-negative and penicillinase-producing strains; streptococcus pneumoniae; Escherichia coli; Proteus mirabilis; Klebsiella species, Haemophilus influenzae; Branhamella catarrhalis.

Most strains of enterococci (streptococcus faecalis) and a few strains of staphylococci are resistant to cefalexin. Cefalexin is not active against most strains of enterobacter species, morganella morganii, pseudomonas or herellea species.

4.2 Posology and method of administration

Adults

1-4 g daily in divided doses; most infections will respond to a dosage of 500 mg every 8 hours.
For skin and soft tissue infections, streptococcal pharyngitis and mild, uncomplicated urinary tract infections, the usual dosage is 250 mg every 6 hours, or 500 mg every 12 hours.

More severe infections, or those caused by less susceptible organisms may need larger doses. If daily doses greater than 4g are required other parenteral cephalosporins, in appropriate doses, should be considered.

Elderly
As for adults although dosage should be reduced to a daily maximum of 500mg if renal function is severely impaired (glomerular filtration rate < 10ml/min).

Children
The recommended daily dosage for children is 25-50 mg/kg in divided doses.
In the case of skin, 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: Not recommended
Children 5 years and over: 250 mg every 8 hours.
In severe infections, the dosage may be doubled.

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

Route of administration
Oral

4.3 Contraindications

Cefalexin is contraindicated in patients with known allergy to the cephalosporins group of antibiotics. Cefalexin is contra-indicated in patients with porphyria.

4.4 Special warnings and precautions for use

If an allergic reaction to cefalexin occurs the drug should be discontinued and the patient treated with the appropriate agents. Prolonged use of cefalexin may result in the overgrowth of non-susceptible organisms. Careful observation of the patient during therapy is essential and appropriate action should be taken should superinfection occur.

Pseudomembranous colitis (ranging in severity from mild to life-threatening) has been reported in association with use of virtually all broad -spectrum antibiotics, including macrolides, semi-synthetic penicillins and cephalosporins. Therefore, it is essential to take this into account during diagnosis of patients who develop diarrhoea during antibiotic therapy. Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone whilst in more severe cases, appropriate measures should be taken.

Cefalexin should be administered with caution in the presence of markedly impaired renal function. Careful clinical and laboratory studies should be made because safe dosage may be lower than that usually recommended.

A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets. Positive direct Coombs' tests have been reported during treatment with cephalosporin antibiotics. In haematological studies, or in transfusion cross-matching procedures when anti globulin tests are performed on the minor side, or in Coombs' testing of newborn babies whose mothers have received cephalosporin antibiotics before parturition, it should be noted that a positive Coombs' test may be due to the drug.

4.5 Interaction with other medicinal products and other forms of interaction

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 the cephalosporins. Patients have had severe reactions (including anaphylaxis) to both drugs.

Probenecid causes reduced excretion of cefalexin leading to increased plasma concentrations. Cephalosporins may have an increased risk of nephrotoxicity in the presence of amphotericin, loop diuretics, aminoglycosides, capreomycin or vancomycin.

4.6 Fertility, Pregnancy and lactation

Although laboratory and clinical studies have shown no evidence of teratogenicity, caution should be exercised when prescribing for the pregnant patient. Caution should be exercised in administration to a nursing mother.

Following a 500mg dose, levels of 4 micrograms/ml have been detected in breast milk.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Gastro-intestinal - nausea, vomiting, dyspepsia, and abdominal pain have occurred. Diarrhoea has been
reported most frequently. It is rarely severe enough to warrant cessation of therapy. Colitis, including are symptoms of pseudomembranous colitis, may occur during or after treatment. Hypersensitivity - allergies (in the form of rash, urticaria and angio-oedema) have been observed. Also erythema multiforme, Stevens-Johnson syndrome usually subside upon discontinuation of the drug, although supportive therapy may be needed in some cases. Serum sickness-like reactions with rashes and fever have been reported.

Anaphylaxis has also been reported.

Haematological - eosinophilia, neutropenia, thrombocytopenia leucopenia, agranulocytosis, aplastic anaemia and haemolytic anaemia have been reported. Slight elevations of AST and ALT have been observed.

Hepatic - transient hepatitis and cholestatic jaundice have been reported rarely.

Miscellaneous - other reactions have included genital and anal pruritus, genital candidiasis, vaginitis and vaginal discharge, dizziness, fatigue and headache. Agitation, confusion, hallucinations, arthralgia, arthritis and joint disorder. Hyperactivity, nervousness, sleep disturbances and hypertonia have also been reported.

Reversible interstitial nephritis has been reported rarely and toxic epidermal necrolysis have been observed rarely.

4.9 Overdose

Symptoms reported include nausea, vomiting, diarrhoea, epigastric distress and haematuria. In instances where children have accidentally ingested more than 3.5g cefalexin in a day, there have been associated reports of haematuria, without impairment of renal function. Treatment has been supportive (fluids) and no sequelae have been reported.

Severe overdosage - General supportive care is recommended, including close clinical and laboratory
monitoring of haematological, renal and hepatic functions, and coagulation status until the patient is stable.

The following clinical measures are extremely unlikely to be indicated in the event of cefalexin overdose and have not been established as beneficial in this situation: forced diuresis, peritoneal dialysis, haemodialysis or charcoal haemoperfusion.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cefalexin is bactericidal and has antimicrobial activity similar to that of cephaloridine or cephalothin against both grampositive and gram-negative organisms.

5.2 Pharmacokinetic properties

Cefalexin is almost completely absorbed from the gastro-intestinal tract and produces peak plasma concentrations about 1 hour after administration. A dose of 500 mg produces a mean peak plasma concentration of about 18 micrograms per ml, about the same as the

concentration produced by an equal dose of cephaloridine given intramuscularly and greater than that produced by cephalothin. If cefalexin is taken with food there is delayed and slightly reduced absorption and there may be delayed elimination from the plasma. About 10 to 15% of a dose is bound to plasma proteins.

The biological half-life has been reported to range from 0.6 to at least 1.2 hours and this increases with reduced renal function. About 80% or more of a dose is excreted unchanged in the urine in the first 6 hours by glomerular filtration and tubular secretion; urinary concentrations greater than 1 mg per ml have been achieved after a dose of 500 mg. Probenecid delays urinary excretion and has been reported to increase biliary excretion. Cefalexin is widely distributed in the body but does not enter the cerebrospinal fluid in significant quantities unless the meninges are inflamed. It diffuses across the placenta and small quantities are found in the milk of nursing mothers. Therapeutically effective concentrations may be found in the bile.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised Starch
Colloidal Anhydrous Silica
Magnesium Stearate E 572
Microcrystalline Cellulose E460

Coating
Hydroxypropyl Methylcellulose E 469
Polyethylene Glycol E1521
Titanium Dioxide (E171)
Erythrosine Lake (E127)
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.
Keep the container tightly closed (for bottles).
Store in the original package (for blisters).

6.5 Nature and contents of container

Polypropylene tubular container with an open end equipped to accept a polyethylene closure, with tamper evident strip containing 7, 14, 20, 21, 28, 30, 50,56, 60, 100 or 500 tablets or PVC/Aluminium blisters or

PVdC coated PVC/Aluminium blisters (60g/m²PVdC on 250µm PVC/20µm Al) containing 7, 14, 20, 21, 28, 30, 50, 56, 60, 100 or 500 tablets. They come in bulk packs of 30, 50, 100 and 500 as well as blisters of 21 and 28 tablets. Not all packs are marketed.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 49565/0033

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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