

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Keftid Capsules 500 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per Capsule

Cefaclor Monohydrate	
Equivalent to Cefaclor	500.00mg

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard
Size 0, elongated purple and grey hard gelatin capsules overprinted CEF500 in gold, filled with homogeneous white to slightly yellow powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Cefaclor is indicated for the treatment of infections caused by sensitive microorganisms, including infections of the upper and lower respiratory tract and middle ear including *Streptococcus pyogenes* (group A beta haemolytic streptococci), *Branhamella catarrhalis*.

4.2 Posology and method of administration

The route of administration is oral.

Adults:

250mg every eight hours, may be doubled to 500mg every eight hours for more severe infections. Total daily dosage should not exceed 4g.

Children:

20mg/kg/day in divided doses every eight hours. This may be increased to 40mg/kg/day in divided doses in otitis media, sinusitis, more serious infections and those caused by less susceptible bacteria. In otitis media and pharyngitis the total daily dosage may be divided and given every twelve hours.

Total daily dosage should not exceed 1g.

In infections caused by beta-haemolytic streptococci, treatment should be continued for at least 10 days.

The safe use of cefaclor in babies aged below one month has not been proven.

Elderly:

The normal adult dose is appropriate.

Patients Undergoing Haemodialysis:

Due to a 25-30% decrease in plasma half-life, a loading dose of 250mg - 1g before dialysis is recommended with a maintenance dose between dialysis sessions of 250mg - 500mg every six to eight hours.

4.3 Contraindications

Cefaclor should not be used in patients with known or suspected hypersensitivity to cephalosporins.

4.4 Special warnings and precautions for use

Prolonged use of an anti-infective may result in the development of super-infection due to the emergence of resistant organisms.

Before instituting therapy with cefaclor, every effort should be made to determine whether the patient has had previous hypersensitivity reactions to cefaclor, cephalosporins, penicillins or other drugs. Cefaclor should be given cautiously to penicillin-sensitive patients, because cross-hypersensitivity, including anaphylaxis, among beta-lactam antibiotics has been clearly documented.

If an allergic reaction to cefaclor occurs, the drug should be discontinued and the patient treated with the appropriate agents.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics, including macrolides, semi-synthetic 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 usually respond to drug discontinuance alone. In moderate to severe cases, appropriate measures should be taken.

Cephalosporin antibiotics may cause a positive result in Coombs' testing. When Coombs' testing is performed on neonates whose mothers received cephalosporins prior to labour, it should be noted that a positive result may be due to the drug. This should also be borne in mind during anti-globulin testing for haematological or cross-matching procedures. Cefaclor may also cause a false positive urine glucose result when Benedict's or Fehling's solutions or copper sulphate tablets are used in the testing.

Cefaclor should be administered with caution in the presence of markedly impaired renal function since the half life of cefaclor in anuric patients is 2.3 to 2.8 hours. Dosage adjustments for patients with moderate or severe renal impairment are not usually required. Clinical experience with cefaclor under such conditions is limited, therefore careful clinical observation and laboratory studies should be made.

4.5 Interaction with other medicinal products and other forms of interaction

The anticoagulant effect of warfarin may be enhanced by simultaneous treatment with cefaclor therefore prothrombin times should be monitored and warfarin dosage adjusted if necessary.

The excretion of all cephalosporins may be reduced by concomitant administration of probenecid leading to increased plasma cephalosporin concentrations.

Cefaclor may decrease the efficacy of estrogen-containing oral contraceptives.

4.6 Fertility, pregnancy and lactation

Cefaclor should not be administered during pregnancy or lactation unless considered essential by the physician.

Animal studies have shown no teratogenic effects. However, care should be taken as there is inadequate data on the safety of cefaclor in pregnant women. Studies during lactation have detected trace amounts in breast milk (0.2 microgram/ml up to 5 hours after an oral dose of 500mg). As the effect on the infant is not known, care is required if cefaclor is administered during lactation.

4.7 Effects on ability to drive and use machines

Cefaclor does not affect the ability to drive or operate machinery.

4.8 Undesirable effects

Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $\leq 1/100$); rare ($\geq 1/10,000$ to $\leq 1/1,000$); very rare ($\leq 1/10,000$), not known (cannot be estimated from the available data).

Infections and infestations

Frequency not known; Genital pruritus and vaginitis.

Blood and the lymphatic system disorders

Rare: Thrombocytopenia, transient lymphocytosis and leucopenia. Other haematological reactions include haemolytic anaemia, aplastic anaemia, agranulocytosis and reversible neutropenia.

Frequency not known: eosinophilia

Immune system disorders

Rare: Allergic reactions, usually resolving when treatment is stopped, (for example pruritus, urticaria and morbilliform eruptions).

Frequency not known: Serum sickness-like reactions in the form of erythema multiforme minor, arthritis/arthralgia and/or fever. This type of reaction is probably a hypersensitivity reaction and has usually developed with second and subsequent courses of cefaclor. Symptoms usually develop a few days after commencing treatment with cefaclor and disappear within a few days of stopping the drug. Symptom resolution can be aided with the administration of antihistamines and corticosteroids. Serious sequelae have not been reported. This reaction has been reported most often in children.

Psychiatric disorders

Frequency not known: nervousness, confusion, insomnia, hypertonia, reversible hyperactivity and hallucinations

Nervous system disorders

Common: Headache

Frequency not known: Dizziness, drowsiness,

Gastrointestinal disorders

Rare: pseudomembranous colitis

Common: Diarrhoea (not usually severe enough to discontinue treatment), Colitis, Nausea, Vomiting, Abdominal discomfort

Hepato-biliary disorders

Frequency not known: Transient hepatitis and cholestatic jaundice

Skin and subcutaneous tissue disorders

Rare: Stevens-Johnson syndrome (erythema multiforme major), toxic epidermal necrolysis and anaphylaxis (which may be more common in patients allergic to penicillins).

Renal and urinary disorders

Rare: reversible interstitial nephritis, slight elevations in blood urea or serum creatinine and abnormal urine test results.

General disorders and administration site conditions

Frequency not known: positive Coomb's tests,

Rare: Slight elevations in ALT, AST and alkaline phosphatase

It should be noted that there is a lack of modern frequency data for cefaclor adverse events.

4.9 Overdose

The symptoms of Cefaclor overdose are non-specific and are generally nausea, vomiting, diarrhoea and gastric upsets.

Treatment for Cefaclor overdose is mainly supportive. If a large amount has been ingested (more than 5 times the normal daily dose) then gastric lavage will be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cefaclor is a broad-spectrum, second generation cephalosporin. It is bactericidal against a wide range of Gram-positive and Gram-negative microorganisms. The reported mode of action is predominantly by the inhibition of cell wall synthesis in susceptible bacteria. This is mainly achieved by inhibiting the trans-peptidation reaction, the final stage of the cell wall synthesis process, thus preventing the complete formation of peptidoglycan cross-links. Other earlier stages in this synthesis process may also be inhibited and there may be some induction of bacterial lysis.

5.2 Pharmacokinetic properties

Cefaclor is well absorbed from the gastro-intestinal tract with oral doses of 250mg and 500mg producing peak plasma concentrations of approximately 6mcg/ml and 13mcg/ml respectively 0.5 to 1 hour post-dosing. The presence of food in the stomach may delay drug absorption but the total amount absorbed is the same. The reported plasma half-life is 0.5 to 1 hour; this may increase slightly in renal failure and is reduced by 25-30% by haemodialysis. Cefaclor is widely distributed in the body and also crosses the placenta. Trace amounts are excreted in breast milk. Cefaclor is rapidly excreted unchanged by the kidneys with up to 85% of an oral dose appearing in the urine within 8 hours. Oral doses of 250mg and 500mg produce peak urine concentrations of 600mcg/ml and 900mcg/ml respectively.

5.3 Preclinical safety data

No further preclinical safety data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised maize starch

Silica, Colloidal Hydrated

Magnesium stearate

Capsule Shell Components :

Gelatin

Indigotine (E132)

Erythrosine (E127)

Black ferric oxide (E172)

Titanium dioxide (E171)

Printing Ink Components:

Shellac
Propylene glycol
Strong ammonia solution
Yellow iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package.

6.5 Nature and contents of container

PVC blister backed by hard-temper aluminium foil containing 3, 15, 21, 50 or 100 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Strides Pharma UK Ltd
Unit 4 Metro Centre
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Watford
WD18 9SS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 0894/004/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 September 1998

Date of last renewal: 18 September 2008

10 DATE OF REVISION OF THE TEXT

August 2017