# Ceflon®

Cefaclor

Powder for Suspension / Powder for Paediatric Drops

## DESCRIPTION

**Ceflon®** is a preparation of Cefaclor, a second generation cephalosporin having greater stability against ß-lactamase inactivation and possesses a broader spectrum of activity.

- It is generally effective in the eradication of *Streptococcus* from the nasopharynx.
- **Ceflon®** is active against the following organisms in vitro:

α-and ß-haemolytic *Streptococci, Staphylococci* (including coagulase-positive, coagulase-negative and penicillinase producing strains), *Streptococcus pneumoniae, Streptococcus pyogenes* (group A ß-haemolytic Streptococci), *Branhamella catarrhalis, Escherichia coli, Proteus mirabilis, Klebsiella* species, *Haemophilus influenzae* (including ampicillin resistant strains), *Neisseria gonorrhoeae*.

## INDICATIONS

**Ceflon®** is indicated for the treatment of the following infections due to susceptible micro-organisms

- Respiratory tract infections, including pneumonia, bronchitis, exacerbation of chronic bronchitis, pharyngitis and tonsillitis.
- As part of the management of sinusitis.
- Otitis media.
- Skin and soft tissue infections.
- Urinary tract infections (It has been found to be effective in both acute and chronic urinary tract infections), including pyelonephritis and cystitis.

## DOSAGE AND ADMINISTRATION

**Adult:** The usual adult dose is 250 mg every eight hours. For more severe infections or those caused by less susceptible organisms, doses may be doubled. Doses of 4g per day have been administered safely to normal subjects for 28 days, but the total daily dose should not exceed this amount.

**Impaired renal function:** It may be administered in the presence of impaired renal function. Under such conditions dose is usually unchanged.

Patients undergoing haemodialysis; a loading dose of 250 mg to 1g administered prior to dialysis and a therapeutic dose of 250 to 500 mg every six to eight hours maintained during interdialytic periods is recommended.

**Elderly:** As for adults.

**Children:** The usual recommended daily dosage for children over one month of age is 20 mg/kg/day in divided doses every eight hours, as indicated. For more serious infections and infections caused by less susceptible organisms, 40 mg/kg/day in divided doses are recommended, with a maximum dosage of 1g/day. Safety and efficacy have not been established for use in infants aged less than one month. Another recommendation is as follows:

| Age | Ceflon Suspension (125 mg/5mL) | Ceflon Paediatric Drops (125 mg/1.25 mL) |
|---|---|---|
| <1 year (9kg) | 2.5 mL t.i.d | 0.625 mL t.i.d |
| 1-5 years (9kg-18kg) | 5.0 mL t.i.d | 1.25 mL t.i.d |
| Over 5 years | 10 mL t.i.d | |

**Note:** In more serious infections, otitis media, sinusitis and infections caused by less susceptible organisms 40 mg/kg/day in divided doses is recommended, upto a daily maximum of 1g. In the treatment of ß-haemolytic streptococcal infections, therapy should be continued for at least 10 days.

**Treatment:** Unless 5 times the normal total daily dose has been ingested, gastro-intestinal decontamination will not be necessary. General management may consist of supportive therapy.

## USE IN PREGNANCY AND LACTATION

**Pregnancy:** Animal studies have shown no evidence of impaired fertility or teratogenicity. However, since there are no adequate or well-controlled studies in pregnant women, caution should be exercised when prescribed for the pregnant women.

**Lactating mothers:** Small amounts of Cefaclor have been detected in breast milk following administration of single 500 mg doses. As the effect on nursing infant is not known, caution should be exercised when Cefaclor is administered to nursing women.

## SIDE-EFFECTS

***Gastro-intestinal:*** The most frequent side effect is diarrhoea, nausea, vomiting and abdominal discomfort have also been reported.

***Hypersensitivity:*** Allergic reactions such as morbiliform eruptions, pruritus and urticaria have been observed. These reactions usually subside upon discontinuation of therapy. Serum sickness-like reactions have been reported and have usually occured during or following a second (or subsequent) course of therapy with Cefaclor. Such reactions have been reported more frequently in children than adults. There are reports of erythema multiforme major (Stevens-Johnson syndrome), toxic epidermal necrolysis, and anaphylaxis. Anaphylaxis may be more common in patients with history of penicillin allergy.

***Haematological:*** Eosinophilia, thrombocytopenia, transient lymphocytosis, leucopenia and rarely haemolytic anaemia, aplastic anaemia, agranulocytosis and reversible neutropenia.

Hepatic Transient hepatitis and cholestatic jaundice have been reported rarely.

***Renal:*** Reversible interstitial nephritis has occurred rarely, also slight elevations in blood urea or serum creatinine or abnormal urinalysis.

***Central Nervous system:*** Reversible hyperactivity, nervousness, insomnia, confusion, hypertonia, dizziness, hallucinations and somnolence have been reported rarely.

***Miscellaneous:*** Genital pruritus, vaginitis and vaginal moniliasis.

## CONTRAINDICATION

Hypersensitivity to cephalosporins.

## DRUG INTERACTIONS

There have been rare reports of increased prothrombin time, with or without clinical bleeding, in patients receiving Cefaclor and warfarin concomitantly. It is recommended that in such patients, regular monitoring of prothrombin time should be considered, with adjustment of dosage if necessary. The renal excretion of Cefaclor is inhibited by probenecid.

## WARNINGS

Before instituting therapy with Celaclor, every effort should be made to determine whether the patients has had previous hypersensitivity reactions to Cefaclor, cephalosporins, penicillins or other drugs.

## PRECAUTIONS

**Ceflon®** should be administered with caution in the presence of markedly impaired renal function. Dosage adjustments for patients with moderate or severe renal impairment are not usually required.

## PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of the reach of children.

## PACKAGING

**Ceflon® Powder for Suspension** : Bottle containing powder for the preparation of 100 mL suspension. After reconstitution each 5 mL contains Cefaclor Monohydrate BP equivalent to Cefaclor 125 mg.

**Ceflon® Powder for Paediatric Drops** : Bottle containing powder for the preparation of 15 mL suspension. After reconstitution each 1.25 mL contains Cefaclor Monohydrate BP equivalent to Cefaclor 125 mg.

SK+F

Manufactured by

**ESKAYEF PHARMACEUTICALS LTD.**

TONGI, GAZIPUR, BANGLADESH

® REGD. TRADEMARK

PM00153 V03