



COMPOSITION :-

Each 5 mL (when mixed with water as recommended) contains:

Cefaclor (as monohydrate) 125 mg, 250 mg

DESCRIPTION :-

Creamy white to slightly yellow powder which reconstituted to pink suspension.

PHARMACODYNAMICS & PHARMACOKINETICS :-

Sifactor® (Oral Suspension) is a formulation of cefaclor which is a semi-synthetic cephalosporin antibiotic (second generation) for oral administration. It inhibits bacterial cell wall synthesis by binding to one or more of the penicillin-binding proteins (PBPs) which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Cefaclor has been shown to be active against gram-positive cocci and some gram-negative bacterial strains such as group A *β-hemolytic streptococcus*, penicillin sensitive and penicillin resistant staphylococci, *E. coli*, *Klebsiella pneumoniae*, *Neisseria gonorrhoea*, *Proteus mirabilis* and *H. Influenzae*. Cefaclor is acid stable and well absorbed after oral administration. It widely distributes throughout the body and reaches therapeutic concentration in most tissue and body fluid, including synovial, pericardial, pleural, and peritoneal fluids; also bile, spectrum and urine; also bone, myocardium, gallbladder, skin and soft tissue; crosses the placenta and appears in breast milk.

INDICATIONS :-

Sifactor® (Oral Suspension) is indicated in the treatment of the following infections: otitis media, respiratory tract infections, skin and soft tissue infections, and genitourinary infections.

DOSAGE AND ADMINISTRATION :-

Adults :

The usual dosage is 250-500 mg every 8 hours (three times daily) or as prescribed by physician.

Children :

The usual recommended dosage is 20 mg/kg/day in divided dose every 8-12 hours. For more serious infections, otitis media and infections caused by less susceptible organisms, 40 mg/kg/day is

recommended, with a maximum dosage of 1 g/day. Total daily dose may be divided into two or three doses or as prescribed by physician.

Child's weight (kg)	Sifactor® (Oral Suspension)	
	125 mg/5 mL	250 mg/5 mL
20 mg/kg/day		
9	1/2 tsp, 3 times a day	-
18	1 tsp, 3 times a day	1/2 tsp, 3 times a day
40 mg/kg/day		
9	1tsp, 3 times a day	1/2 tsp, 3 times a day
18	-	1 tsp, 3 times a day

ROUTE OF ADMINISTRATION :-

Oral

PREPARATION OF ORAL SUSPENSION :-

Sifactor® (Oral Suspension) : To make up first shake bottle to loosen powder, add the volume of water less than the line on the bottle label, keep tightly closed and shake well, then fill up to the line. Once reconstituted, the suspension must be stored in a refrigerator and used within 14 days. Shake well before taking each dose.

DRUG INTERACTIONS :-

Patients receiving Sifactor® (Oral Suspension) may show a false positive reaction for glucose in the urine with tests that use Benedict's and Fehling's solutions and also with Clinitest tablets. Anticoagulant effect is increased when Sifactor® (Oral Suspension) and oral anticoagulants are administered concomitantly. The renal excretion of cefaclor is inhibited by probenecid as with other β -lactam antibiotics.

CONTRAINDICATIONS :-

Sifactor® (Oral Suspension) should not be used in patients with known allergy to the cephalosporin group of antibiotics.

PRECAUTIONS / WARNINGS :-

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous

Actual Size 100 %

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adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Sifactor® (Oral Suspension), careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Sifactor® (Oral Suspension) must be discontinued immediately and appropriate alternative therapy instituted.

Sifactor® (Oral Suspension) should be administered with caution in the presence of markedly impaired renal function. Prolonged use may result in superinfection. Positive direct Coomb's test may be occurred during treatment with Sifactor® (Oral Suspension) It should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

PREGNANCY AND LACTATION :-

Use in pregnancy : Sifactor® (Oral Suspension) should be used during pregnancy only if clearly needed (Risk Factor 3)

Use in lactation : Small amounts have been detected in mother's milk following administration of single 500 mg doses. The effect on nursing infants is not known.

SIDE EFFECTS :-

Although, the majority of adverse reactions were mild and transient, drug-related adverse reactions were considered to be occurred in therapy with cefaclor as shown below :

Hypersensitivity :

Rash, urticaria or pruritus may occur. Serum-sickness-like reactions have been reported. These are characterized by findings of erythema multiforme, rashes and other skin manifestations with arthritis/arthralgia, fever (may occur), and differ from classic serum sickness. More severe hypersensitivity reactions including Stevens-Johnson Syndrome, toxic epidermal necrolysis, and anaphylaxis have been reported rarely.

Gastrointestinal :

Diarrhea and dyspepsia may occur. Nausea and vomiting have been reported rarely. Like some penicillins and other cephalosporins, transient hepatitis and cholestatic jaundice have been reported. Pseudomembranous colitis symptoms may occur during or after antibiotic treatment. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Genitourinary :

Vaginal moniliasis and vaginitis have been reported.

Central Nervous System :

Headache, dizziness and somnolence have been reported.

Hematological :

β -lactam antibiotics, agranulocytosis and reversible neutropenia of possible clinical significance have been reported rarely.

Hepatic :

Slight elevation of transaminases may occur.

Renal :

Slight elevation in BUN or Serum Creatinine or abnormal urinalysis have been reported.

OVERDOSAGE & TREATMENT :-

The toxic symptoms following an overdose of Sifactor® (Oral Suspension) may include nausea, vomiting, epigastric distress and diarrhea. The severity of the epigastric distress and the diarrhea is dose-related. Treatment : There is no specific antidote for treatment of overdose with Sifactor® (Oral Suspension). Treatment is symptomatic and supportive. Gastric lavage may be useful.

SHELF LIFE :-

2 years

STORAGE :-

Keep tightly closed and store below 30°C
Once reconstituted, the suspension must be stored in a refrigerator (2-8°C), and used within 14 days. Shake well before taking each dose.

PACKINGS :-

Powder for oral suspension : 125 mg/5 mL (60 mL) ;
250 mg/5 mL (60 mL)

Date of revision : 30/01/2023

Manufacturer :-

Siam Bheasach Co., Ltd.

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Product Registration Holder, Importer :-

SPG PHARMA (MALAYSIA) SDN. BHD.

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