SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cefaclor 125mg/5ml

Distaclor 125mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of reconstituted suspension contains as the active ingredient, cefaclor monohydrate Ph.Eur. equivalent to 125mg of cefaclor base.

Excipient(s) with known effect: Sucrose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Granules for Oral Suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Distaclor is indicated for the treatment of the following infections due to susceptible micro-organisms:

Respiratory tract infections, including pneumonia, bronchitis, exacerbations of chronic bronchitis, pharyngitis and tonsillitis, and as part of the management of sinusitis

Otitis media

Skin and soft tissue infections

Urinary tract infections, including pyelonephritis and cystitis. Distaclor has been found to be effective in both acute and chronic urinary tract infections.

Cefaclor is generally effective in the eradication of streptococci from the nasopharynx, however, data establishing efficacy in the subsequent prevention of either rheumatic fever or bacterial endocarditis are not available.

4.2 Posology and method of administration

Posology

Paediatric population:
The usual recommended daily dosage for children is 20mg/kg/day in divided doses every eight hours, as indicated. For bronchitis and pneumonia, the dosage is 20mg/kg/day in divided doses administered 3 times daily. For otitis media and pharyngitis, the total daily dosage may be divided and administered every 12 hours. Safety and efficacy have not been established for use in infants aged less than one month.

Distaclor Suspension

	125mg/5ml	250mg/5ml
<1 year (9kg)	2.5ml tid	
1-5 years (9-18kg)	5.0ml tid	
Over 5 years		5.0ml tid

In more serious infections, otitis media, sinusitis and infections caused by less susceptible organisms, 40mg/kg/day in divided doses is recommended, up to a daily maximum of 1g.

In the treatment of beta-haemolytic streptococcal infections, therapy should be continued for at least 10 days.

For instructions on dilution of the medicinal product before administration, see section 6.6.

Adults: The usual adult dosage is 250mg 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 dosage should not exceed this amount.

Distaclor may be administered in the presence of impaired renal function. Under such conditions dosage is usually unchanged (see section 4.4. 'Special warnings and precautions for use').

Patients undergoing haemodialysis. Haemodialysis shortens serum half-life by 25- 30%. In patients undergoing regular haemodialysis, a loading dose of 250mg-lg administered prior to dialysis and a therapeutic dose of 250-500mg every six to eight hours maintained during interdialytic periods is recommended.

The elderly: As for adults.

Method of administration

Distaclor is administered orally.

4.3 Contraindications

Hypersensitivity to the active substance, any cephalosporins or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Warnings

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.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose – isomaltase insufficiency should not take this medicine.

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 diagnosisin 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.

Precautions

Reports of neurotoxicity have been identified in association with cephalosporin treatment. Symptoms may include encephalopathy, myoclonus and seizures. Elderly patients, patients with severe renal impairment or central nervous system disorders are particularly at risk. 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 (compared to 0.6-0.9 hours in normal subjects), 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. If cefaclor associated neurotoxicity is suspected, discontinuation of cefaclor should be considered.

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastro- intestinal disease, particularly colitis.

Prolonged use of cefaclor may result in the overgrowth of non-susceptible organisms. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the 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 newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognised that a positive Coombs' test may be due to the drug.

A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets.

This medicinal product contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially ‘sodium-free’

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.6 Fertility, 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 prescribing for the pregnant patient.

Breastfeeding: Small amounts of cefaclor have been detected in breast milk following administration of single 500mg doses. Average levels of about 0.2 micrograms/ml or less were detected up to 5 hours later. Trace amounts were detected at one hour. As the effect on nursing infants is not known, caution should be exercised when cefaclor is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

Gastro-intestinal: The most frequent side-effect has been diarrhoea. It is rarely severe enough to warrant cessation of therapy. Colitis, including rare instances of pseudomembranous colitis, has been reported.
Nausea and vomiting have also occurred.

Hypersensitivity: Allergic reactions such as morbilliform eruptions, pruritus and urticaria have been observed. These reactions usually subside upon discontinuation of therapy. Serum sickness-like reactions (erythema multiforme minor, rashes or other skin manifestations accompanied by arthritis/arthralgia, with or without fever) have been reported. Lymphadenopathy and proteinuria are infrequent, there are no circulating immune complexes and no evidence of sequelae. Occasionally, solitary symptoms may occur, but do not represent a serum sickness-

like reaction. Serum sickness-like reactions are apparently due to hypersensitivity and have usually occurred during or following a second (or subsequent) course of therapy with cefaclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and usually subside within a few days of cessation of therapy. Antihistamines and corticosteroids appear to enhance resolution of the syndrome. No serious sequelae have been reported.

There are rare reports of erythema multiforme major (Stevens-Johnson syndrome), toxic epidermal necrolysis, and anaphylaxis. Anaphylaxis may be more common in patients with a history of penicillin allergy. Anaphylactoid events may present as solitary symptoms, including angioedema, asthenia, oedema (including face and limbs), dyspnoea, paraesthesias, syncope, or vasodilatation.

Rarely, hypersensitivity symptoms may persist for several months.

Haematological: Eosinophilia, positive Coombs' tests and, rarely, thrombocytopenia. Transient lymphocytosis, leucopenia and, rarely, haemolytic anaemia, aplastic anaemia, agranulocytosis and reversible neutropenia of possible clinical significance. See section 4.5 'Interactions with other medicinal products and other forms of interaction'.

Hepatic: Transient hepatitis and cholestatic jaundice have been reported rarely, slight elevations in AST, ALT or alkaline phosphatase values.

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

Central Nervous System: Reversible hyperactivity, agitation, nervousness, insomnia, confusion, hypertonia, dizziness, hallucinations and somnolence have been reported rarely. There have been reports of neurological sequelae including tremor, myoclonia, convulsions, encephalopathy with drugs belonging to the class of cephalosporins. Most cases occurred in patients with renal impairment who received doses that exceeded the recommended dose and resolved following discontinuation of treatment.

Miscellaneous: Genital pruritus, vaginitis and vaginal moniliasis.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continues monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms of nausea, vomiting, epigastric distress and diarrhoea would be anticipated.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Second-generation cephalosporins, ATC code: J01DC04

Cefaclor is active against the following organisms *in vitro:*

Alpha- and beta-haemolytic streptococci

Staphylococci; including coagulase-positive, coagulase-negative and penicillinase-producing strains

Streptococcus pneumoniae

Streptococcus pyogenes (group A beta-haemolytic streptococci)

Branhamella catarrhalis

Escherichia coli

Proteus mirabilis

Klebsiella species

Haemophilus influenzae, including ampicillin-resistant strains.

Cefaclor has no activity against *Pseudomonas* species or *Acinetobacter* species. Methicillin-resistant staphylococci and most strains of enterococci (eg, *Str. faecalis)* are resistant to cefaclor. Cefaclor is not active against most strains of *Enterobacter* spp, *Serratia* spp, *Morganella morganii, Proteus vulgaris* and *Providencia rettgeri.*

5.2 Pharmacokinetic properties

Cefaclor is well absorbed after oral administration to fasting subjects. Total absorption is the same whether the drug is given with or without food; however, when it is taken with food, the peak concentration achieved is 50-75% of that observed when the drug is administered to fasting subjects and generally appears from ¾ to one hour later. Following administration of 250mg, 500mg and 1G doses to fasting subjects, average peak serum levels of approximately 7, 13 and 23 mg/L respectively were obtained within 30 - 60 minutes. Approximately 60 - 85% of the drug is excreted unchanged in the urine within eight hours, the greater portion being excreted within the first two hours. During the eight hour period, peak urine concentrations following the 250mg, 500mg and 1G doses were approximately 600, 900 and 1,900 mg/L respectively. The serum half-life in normal subjects is 0.6 - 0.9 hours. In patients with reduced renal function, the serum half-life of cefaclor is slightly prolonged. In those with complete absence of renal function, the plasma half-life of the intact molecule is 2.3 - 2.8 hours. Excretion pathways in patients with markedly

impaired renal function have not been determined. Haemodialysis shortens the half-life by 25 - 30%.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Erythrosine aluminium lake
Methylcellulose 15
Sodium Lauryl Sulphate
Artificial Strawberry Flavour
Dimeticone
Xanthan Gum F
Starch Modified

6.2 Incompatibilities

None Known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25 °C. Keep containers tightly closed and protect from light. After reconstitution, the suspension should be stored in a refrigerator (2-8ºC) and be used within 14 days.

6.5 Nature and contents of container

The product is filled into high density polyethylene bottles with screw caps containing 100ml of Cefaclor suspension.

6.6 Special precautions for disposal and other handling

When dilution is unavoidable, syrup BP should be used after the suspension has been prepared according to the manufacturer's instruction.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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40 Mespil Road,

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IRELAND, D04 C2N4

8 MARKETING AUTHORISATION NUMBER(S)

PL 13621/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/08/1978

10 DATE OF REVISION OF THE TEXT

03/12/2025