SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cefadroxil125 mg/5 ml Powder for Oral Suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of the reconstituted suspension contains Cefadroxil USP equivalent to Cefadroxil anhydrous 125 mg.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Infections caused by microorganisms susceptible to Cefadroxil: infections of the urinary tract, infections of the skin and soft tissues, and infections of the upper respiratory tract.

Consideration should be given to official local guidance or recommendations regarding the appropriate use and prescription of antibacterial agents.

4.2 Posology and Method of Administration

Posology

Adults and children (>40 kg): Infections of the upper respiratory tract, infections of the skin and soft tissues, and infections of the urinary tract: usual dose 500 mg – 1 g twice a day.

Children <40 kg – Streptococcal tonsillitis, infections of the skin and soft tissues: 30 mg/kg body weight once daily.

Weight (kg)	Age (years)	Dosage suspension (125 mg/5 ml)
<10	<1	12 ml x 1
10–20	1–5	24 ml x 1
20–30	5–10	36 ml x 1
30–40	10–12	48 ml x 1

Uncomplicated urinary tract infections: 12.5 mg/kg body weight twice daily.

Weight (kg)	Age (years)	Dosage suspension (125 mg/5 ml)
<10	<1	5 ml x 2
10–20	1–5	10 ml x 2
20–30	5–10	15 ml x 2
30–40	10–12	20 ml x 2

Serious infections (e.g. urinary tract and respiratory tract infections): 25 mg/kg body weight twice daily.

Weight (kg)	Age (years)	Dosage suspension (125 mg/5 ml)
<10	<1	10 ml x 2
10–20	1–5	20 ml x 2
20–30	5–10	30 ml x 2
30–40	10–12	40 ml x 2

Treatment should be applied for 2 to 3 further days after clinical symptoms fade away. In the case of streptococcal infections, a minimum of 10 days is recommended.

Impaired kidney function: The half-life in plasma is prolonged with impaired kidney function. The recommended dose is 500 mg, but the interval between doses should be increased. With a creatinine clearance of 25–50 ml/min a dose may be given every 12 hours; with 10–25 ml/min every 24 hours; and with creatinine clearance of less than 10 ml/min, one dose every 36 hours.

Method of Administration: For oral use. Cefadroxil should be taken with food. The suspension should be shaken well before use. For instructions on reconstitution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

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

4.4 Special Warnings and Precautions for Use

Special caution is called for when known penicillin allergy is present, as cross-allergy may occur. As a consequence of treatment with cephalosporins, in exceptional cases a false positive Coombs test has been reported. During treatment with cefadroxil, a false positive reaction for glucose in the urine may occur when Benedict's or Fehling's solutions, copper sulfate or Clinitest tablets are used in the test, but not in the enzyme test with Clinistix.

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

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- The occurrence of diarrhoea may impair the absorption of other medicaments and therefore lead to an impairment of their efficacy.
- Forced diuresis leads to a decrease of cefadroxil blood levels.
- Cefadroxil should not be combined with bacteriostatic antibiotics (e.g. tetracycline, erythromycin, sulfonamides, and chloramphenicol) since an antagonistic effect is possible.
- Treatment with cefadroxil in combination with aminoglycoside antibiotics, polymyxin B, vancomycin, colistin or high-dose loop diuretics should be avoided since such combinations can potentiate nephrotoxic effects.
- The concomitant administration of probenecid reduces the renal elimination of cefadroxil; therefore, plasma concentrations of cefadroxil may be increased when given in combination with probenecid.

- As with other cephalosporins (in high doses), frequent checks on coagulation parameters are necessary during concomitant long-term use of anticoagulants or thrombocyte aggregation inhibitors to avoid haemorrhagic complications.

4.6 Fertility, Pregnancy and Lactation

Pregnancy: Studies in animals did not reveal any teratogenic effect. In the absence of teratogenic effects in animals, a malformative effect is not expected in humans. In clinical practice, analysis of a large number of exposed pregnancies did not appear to reveal any malformative or foetotoxic effect specifically related to cefadroxil. Consequently, Cefadroxil can be prescribed during pregnancy, if necessary.

Breast-feeding: Low levels of cefadroxil are excreted in breast milk and the ingested quantities are lower than therapeutic doses. Consequently, breast-feeding is possible when taking this antibiotic. However, breast-feeding (or treatment) should be discontinued if the infant develops diarrhoea, candidosis or a skin eruption.

4.7 Effects on Ability to Drive and Use Machines

No effects have been observed.

4.8 Undesirable Effects

The adverse effects are presented according to the frequency of cases: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data). About 6% of patients taking the preparation suffer from undesirable effects.

Infections and infestations: Uncommon: Clinical pictures due to a growth of opportunistic organisms (fungi) such as vaginal mycoses or thrush.

Blood and lymphatic system disorders: Rare: Eosinophilia, thrombocytopenia, leucopenia, neutropenia, agranulocytosis occurring during prolonged use but subsiding upon discontinuation of therapy. Not known: haemolytic anaemia.

Nervous system disorders: Very rare: Headache, dizziness, nervousness, sleeplessness, fatigue.

Gastrointestinal disorders: Common: Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, glossitis. Not known: pseudomembranous colitis has been reported.

Hepatobiliary disorders: Rare: Minor elevation of serum transaminases (ASAT, ALAT) and alkaline phosphatases.

Skin and subcutaneous tissue disorders: Common: Pruritus, rash, allergic exanthema, urticaria. Rare: Angioneurotic oedema, drug fever, serum sickness-like reactions. Very rare: Immediate allergic reaction (anaphylactic shock). Not known: Stevens-Johnson syndrome and erythema multiforme have been reported.

Musculoskeletal and connective tissue disorders: Rare: arthralgia.

Renal and urinary disorders: Rare: interstitial nephritis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Health care professionals are asked to report any suspected adverse reactions via the https://pv.pharmacyboardkenya.org

4.9 Overdose

Toxicity: Acute toxicity varies for different substances but generally speaking appears low. In cases of impaired kidney function, parenteral administration of high doses has given rise to neurological symptoms.

Symptoms: In exceptional cases, anaphylactic shock may occur within 20–40 minutes; a fall in blood pressure with tachycardia or bradycardia, breathing difficulties, nausea, vomiting, exanthema, oedema. Toxic reactions: nausea, vomiting, diarrhoea, electrolytic disorders, reduced consciousness, muscular fasciculations, myoclonia, cramps, coma. Haemolytic reactions: kidney insufficiency, acidosis. Possibly coagulopathy and impairment of already impaired kidney function.

Treatment: When justified: ventricle emptying, charcoal. Symptomatic treatment. Possibly dialysis in toxic reactions and impaired kidney function.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antibacterials for systemic use, other beta-lactam antibacterials, first generation cephalosporins.

Mechanism of Action: Cefadroxil is a semisynthetic cephalosporin derivative for oral administration which inhibits bacterial wall synthesis of actively dividing cells by binding to one or more penicillin-binding proteins. The result is formation of a defective cell wall that is osmotically unstable. Cefadroxil exhibits time-dependent bactericidal activity.

Breakpoints: The following MIC breakpoints are suggested: Susceptible: <1 mg/l; Resistant: >16 mg/l.

Susceptibility:

Susceptible: Betahaemolytic streptococci group A, C, G and B; Staphylococcus aureus[1]; other staphylococci including S. saprophyticus[1]; Streptococcus pneumoniae and anaerobic streptococci.

Intermediately susceptible: E. coli[2]; Klebsiella spp.[2]; Proteus mirabilis[2]; Moraxella catarrhalis[3].

Resistant: Citrobacter spp., Enterobacter spp., Proteus ssp. (indol positive), Serratia spp., Morganella morganii, Campylobacter, Haemophilus influenzae, Pseudomonas spp. including Ps. aeruginosa, Clostridium difficile, Listeria monocytogenes, Legionella, Chlamydia and Mycoplasma spp., Enterococci, anaerobic gram-negative rods.

[1]S. aureus and other staphylococci including beta-lactamase producing strains. [2]E. coli and Klebsiella spp., P. mirabilis: Considered susceptible in lower urinary tract infection. [3]M. catarrhalis: Beta-lactamase producing strains, which are in the majority, are resistant.

All betahaemolytic streptococci are susceptible to beta-lactam antibiotics and no resistance has yet been observed. Cefadroxil cannot be used against gram-positive rods with plasmid mediated beta-lactamase production (TEM, SHV) as the substance will be hydrolysed and inactivated. Penicillin-resistant pneumococci and meticillin-resistant Staphylococcus aureus are resistant to cefadroxil. Resistance can develop during treatment in: Enterobacter, Citrobacter, Pseudomonas (predominantly aeruginosa), Morganella and Serratia.

5.2 Pharmacokinetic Properties

Absorption: Cefadroxil is stable in an acid environment, and is absorbed just as well in conjunction with food as without. Maximal serum concentration (approximately 16 microg/ml after a single dose of 500 mg cefadroxil) is attained about 1.5 hours after ingestion.

Distribution: About 20% of cefadroxil is bound to serum proteins.

Elimination: Cefadroxil is excreted via glomerular filtration and tubular secretion. After 24 hours, approximately 90% of the active substance will have been excreted in the urine. In people with normally functioning kidneys, the half-life of cefadroxil in serum is about 1 hour 20 minutes. After a single dose of 1 g of cefadroxil, sufficient concentrations are present in the urine after 24 hours to combat the most commonly occurring urinary tract pathogens.

5.3 Preclinical Safety Data

There is no preclinical data of relevance for the safety judgement beyond what has already been considered in this Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose, Carmellose Sodium, Colloidal Anhydrous Silica, Sodium Benzoate, Magnesium Stearate, Succinic Acid, Colour Quinoline Yellow WS, Essence Trusil Mango Asv. (Bush).

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months.

6.4 Special Precautions for Storage

The reconstituted suspension should be kept in a cool place and used within 14 days after reconstitution. Keep the container in the outer carton in order to protect from light. Store below 30°C in a tightly closed container.

6.5 Nature and Contents of Container

Bottle of 30 ml, 60 ml & 100 ml.

6.6 Special Precautions for Disposal and Other Handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Indoco House, 166, CST Road, Santacruz (E), Mumbai – 400098, India.

8. MARKETING AUTHORISATION NUMBER(S)

14178

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Not specified.

10. DATE OF REVISION OF THE TEXT

March 2024.