SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ACTIDROX-1000 (Cefadroxil Tablets USP 1000 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Cefadroxil Monohydrate USP

Eq. to Anhydrous Cefadroxil..... 1000 mg

Excipients..... Q.S.

Colour: Titanium dioxide USP (For the full list of excipients, see section 6.1)

3. PHARMACEUTICAL FORM

Film coated tablet.

A white colored, capsule shaped biconvex film coated tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of following infections caused by cefadroxil-susceptible organisms when an oral therapy is indicated

- Streptococcal pharyngitis and tonsillitis
- Bronchopneumonia, bacterial pneumonia
- Uncomplicated urinary tract infections: pyelonephritis, cystitis
- Skin and soft tissue infections: abscesses, furunculosis, impetigo, erysipelas, pyoderma, lymphadenitis Consideration should be given to official local guidance regarding the appropriate use of antibacterial agents.

4.2 Posology and method of administration

The dosage depends on the susceptibility of the pathogens, the severity of the disease and on the clinical status of the patient (renal and hepatic function)

Indication	**Adults and adolescents > 40 kg with normal renal function**
Streptococcal pharyngitis / tonsillitis	Dosage of1000 mg once a day over at least 10 days
Bronchopneumonia, bacterial pneumonia	1000 mg twice a day
Urinary tract infections	1000 mg twice a day
Skin & soft tissue infections	1000 mg twice a day

Renal impairment: The dosage should be adjusted according to creatinine clearance rates to prevent accumulation of cefadroxil. In patients with

creatinine clearance of 50 ml/min or less, the following reduced dosage schedule is recommended as a guideline for adults:

Creatinine clearance (ml/ min/ 1.73 m2)	**Serum Creatinine (mg/100ml)**	**Initial dose**	**Following dose**	**Dosage interval**
50 - 25	1.4 – 2.5	1000 mg	500 mg – 1000 mg	every 12 hours
25 - 10	2.5 – 5.6	1000 mg	500 mg – 1000 mg	every 24 hours
10 - 0	> 5.6	1000 mg	500 mg – 1000 mg	every 36 hours

Mode of administration

Bioavailability is not affected by food and cefadroxil may be taken with meals or on an empty stomach. In case of gastro-intestinal disturbances, it may be administered with food. The tablets are taken with a liberal quantity of fluid.

4.3 Contraindications

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

History of severe reactions to penicillins or to any other beta-lactam drugs

4.4 Special warnings and precautions for use

In patients with a history of non-severe hypersensitivity to penicillins, or other non-cephalosporin beta – lactam drugs, cefadroxil should be used with special caution as cross allergies occur

Renal impairment: Caution is necessary in patients with renal impairment; the dosage must be adjusted according to the grade of renal impairment

History of gastro-intestinal disturbances: Cefadroxil should be used with caution in patients with a history of gastrointestinal disturbances, particularly colitis. The occurrence of diarrhea may impair the resorption of other medicaments and therefore lead to an impairment of their efficacy.

Allergic reactions

Treatment must be discontinued at once if allergic reactions occur (urticaria, exanthema, pruritus, fall of blood pressure and increased heart rate, respiratory disturbances, collapse, etc.) and suitable countermeasures should be taken (sympathomimetics, corticosteroids and/or antihistaminics). In case of severe and persistent diarrhea, an antibiotic-associated pseudomembranous colitis should be considered. In that case Cefadroxil must be discontinued immediately and a suitable therapy should be started (e.g. oral vancomycin, 250 mg q.i.d.). Antiperistaltics are contraindicated.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindication of concomitant use

Cefadroxil should not be combined with bacteriostatic antibiotics (e.g.

tetracycline, erythromycin, sulfonamides, chloramphenicol) since an antagonistic effect is possible.

Treatment with cefadroxil in combination with aminoglycoside antibiotics, polymyxin B, colistin or high-dose loop diuretics should be avoided since such combinations can potentiate nephrotoxic effects.

Concomitant use not recommended

Frequent checks on coagulation parameters are necessary during concomitant long-term use of anticoagulants or thrombocyte aggregation inhibitors to avoid hemorrhagic complications.

Precautions

Cefadroxil binds to cholestyramine which may lead to reduced bioavailability - of cefadroxil.

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.

Cefadroxil may attenuate the effect of oral contraceptives.

4.6 Fertility, pregnancy and lactation

Pregnancy

Although animal studies and clinical experience have not shown any evidence of teratogenicity, the safe use during pregnancy has not been established

Breast-feeding

Cefadroxil is present in low concentrations in breast milk; sensitization, diarrhoea or colonization of the infants' mucosa with fungi are possible. The use of cefadroxil during pregnancy and in lactating mothers should therefore be handled very strictly.

4.7 Effects on ability to drive and use machines

Cefadroxil may cause headache, dizziness, nervousness, sleeplessness and fatigue, therefore the ability to drive and use machines may be influenced

4.8 Undesirable effects

The most common side effects are: Nausea - Vomiting

Diarrhoea

Dyspepsia

Abdominal Pain

Pruritus
Rash

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. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'.

4.9 Overdose

No clinical reports are as yet available on cefadroxil in this respect. However, in view of experience gained with other cephalosporins the following symptoms are possible: nausea, hallucinations, hyperreflexia, extrapyramidal symptoms, clouded consciousness, or even coma and renal functional impairment. First aid after intake of toxic doses: induce vomiting at once or gastric lavage, if necessary, hemodialysis. Monitor and if necessary, correct the water and electrolyte balance, monitor renal function

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other beta-lactam antibacterials. First generation cephalosporins. ATC-Code: J01DB05

Mode of action

Cefadroxil is a cephalosporin for oral administration which inhibits bacterial wall synthesis of actively dividing cells by binding to one or more penicillinbinding proteins. The result is formation of a defective cell wall that is osmotically unstable, and bacterial cell lysis.

Cefadroxil may be active against organisms producing some types of betalactamase, for example TEM-1, in low to moderate quantities

5.2 Pharmacokinetic properties

Absorption

After oral administration cefadroxil is practically completely absorbed. Simultaneous intake of food has practically no effect on absorption (AUC)

Distribution

After oral doses of 500 mg (1000 mg) peak plasma concentrations of about 16 (30) µ g/ml are obtained after 1-1,3 hours. Between 18 and 20% of cefadroxil is bound to plasma proteins. Cephalosporins do not penetrate in the CSF and should not be used for treatment of meningitis.

Biotransformation

Cefadroxil is not metabolised.

Elimination

Cefadroxil is eliminated far more slowly than comparable oral cephalosporins (half-life: about 1,4 h to 2,6 h) so that intervals between doses can be prolonged to 12-24 hours. Roughly 90% of the substance is eliminated in unchanged form through the kidneys within 24 hours. Cefadroxil may be eliminated from the organism through haemodialysis.

Characteristics in patients with reduced creatinine clearance, a sign for renal functional impairment

Elimination is retarded, so that interval between doses must be prolonged.

5.3 Preclinical safety data

Pre-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity, genotoxicity and toxicity to reproduction. 6.0 Pharmaceutical particulars

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone K 30%

Talcum Magnesium stearate

Kyron T-314

Methylene Dichloride

Ready mix of white (Film coating)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C. Protect from direct sunlight, heat and moisture

6.5 Nature and contents of container

1x10 Tablets in an Alu-Alu blister pack

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

KRISHNA CHEMISTS LTD

3rd Floor Metrix Hardware, Lusaka Road, Industrial Area.

8. MARKETING AUTHORISATION NUMBER(S)

CTD3413

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/11/2021

10. DATE OF REVISION OF THE TEXT

10/11/2021