SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cefadroxil Viatris 100 mg/ml powder for oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 mg of cefadroxil (as monohydrate) per 1 ml of reconstituted oral suspension.

Excipient with known effect:
1 ml of reconstituted suspension contains approximately 0.62 g sucrose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral suspension

Powder: white to slightly yellowish powder.
Ready to use suspension: white to slightly yellowish 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,
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 100 mg/ml	Package
<10	<1	3 ml x 1	60 ml
10-20	1-5	6 ml x 1	100 ml
20-30	5-10	9 ml x 1	100 ml
30-40	10-12	10 ml x 1	100 ml

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

Weight (kg)	Age (years)	Dosage Suspension 100 mg/ml	Package
<10	<1	1.25 ml x 2	60 ml
10-20	1-5	2.5 ml x 2	60 ml
20-30	5-10	4 ml x 2	100 ml
30-40	10-12	5 ml x 2	100 ml

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

Weight (kg)	Age (years)	Dosage Suspension 100 mg/ml	Package
<10	<1	2.5 ml x 2	60 ml
10-20	1-5	5 ml x 2	100 ml
20-30	5-10	8 ml x 2	60 + 100 ml
30-40	10-12	10 ml x 2	2 x100 ml

Treatment should be applied 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 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 sucrase-isomaltase insufficiency should not take this medicine. 1 ml of Cefadroxil Viatris oral suspension contains approximately 0.62 g of sucrose. This should be taken into account when doses of 8 ml or above are given to patients with diabetes mellitus.

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.

To present time, substances causing malformation in humans have been shown to be teratogenic in animals during well-conducted studies in two species.

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. However, absence of risk could be confirmed by epidemiological studies.

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 the 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 occur during prolonged use but subside 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. Healthcare professionals are asked to report any suspected adverse reactions via [To be completed nationally].

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 cephlasporins, ATC code: J01DB05.

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.

Susceptibility testing breakpoints
MIC (minimum inhibitory concentration) interpretive criteria for susceptibility testing have been established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for cefadroxil and are listed here: https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx.

All betahaemolytic streptocci are susceptible to beta lactam antibiotics and no resistance has yet been observed. Cefadroxil cannot be used against gram positive rods with plasmid mediated betalactamase production (TEM, SHV) as the substance will be hydrolysed and inactivated. Thus, resistant isolates of E. coli, Klebsiella spp, and P. mirabilis may be encountered.

There can be cross-resistance within the beta lactam antibiotics group (penicillins and cefalosporins).

Penicillin resistant pneumococci and meticillin resistant Staphylococcus aureus are resistant to

cefadroxil.

Resistance can develop during treatment in the following species: Enterobacter, Citrobacter, Pseudomonas (predominately 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 (approx. 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, approx. 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 of cefadroxil are present in the urine after 24 hours to combat the most commonly occurring urinal 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 the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica, colloidal anhydrous, magnesium stearate, guar galactomannan, saccharin, titanium dioxide (E171), talc, sucrose, peach-apricot flavour.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

After reconstitutions (ready prepared oral suspension) 14 days at 2-8°C.

6.4 Special precautions for storage

For storage conditions after reconstitution of the medicinal product, see section 6.3. Keep the container in the outer carton in order to protect from light.

6.5 Nature and contents of container

Powder for oral suspension 100 mg/ml: 60 ml or 100 ml in amber glass bottles (type III) with child resistant screw closure made of polyethylene/polypropylene.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Ready to use suspension: white to slightly yellowish suspension

60 ml of ready for use suspension is obtained by adding 30 ml of water to 45 g of powder.
100 ml of ready for use suspension is obtained by adding 50 ml of water to 75 g of powder.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2025-06-02