1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semelcef 1000 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance:

cefadroxil	1000 mg
Equivalent to cefadroxil monohydrate	1050 mg

Excipients:

Qualitative composition of excipients and other constituents
magnesium stearate
microcrystalline cellulose

Square whitish tablet with two break-marks. The tablet can be divided in two or four equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of the following infections in dogs:
- Skin and soft tissue infections caused by *Staphylococcus* spp. and *Streptococcus* spp. (pyoderma, wounds, abscesses), susceptible to cefadroxil.
- Urinary tract infections caused by *Staphylococcus* spp., *Streptococcus* spp., *Proteus mirabilis, Escherichia coli* and *Klebsiella* spp., susceptible to cefadroxil.
- Upper respiratory tract infections caused by *Staphylococcus* spp., *Streptococcus* spp., and *Pasteurella multocida*, susceptible to cefadroxil.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to other cephalosporins, to other substances of the β-lactam group or to any of the excipients.
Do not use in rabbits, guinea pigs, hamsters, gerbils, chinchillas, equines and ruminants due to possible fatal gastrointestinal disturbances caused by e.g. *Clostridium* spp. overgrowth.

3.4 Special warnings

Pyoderma is usually secondary to an underlying disease. It is advisable to determine the underlying disease to ensure the appropriate treatment is administered.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.
Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefadroxil and may decrease the effectiveness of treatment with penicillins or cephalosporins, due to the potential for cross resistance.

As with other antibiotics which are excreted mainly by the kidneys, unwanted accumulation may occur in the body when renal function is impaired. In cases of known renal insufficiency the veterinary medicinal product should be administered with caution. Antimicrobials known to be nephrotoxic should not be administered concurrently and the veterinary medicinal product should be used only according to a risk/benefit assessment by the responsible veterinarian.

The veterinary medicinal product is not appropriate for animals weighing less than 12.5 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross-reactions to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious. People with known hypersensitivity to cephalosporins or those advised not to be in contact with such substances, should avoid contact with the veterinary medicinal product.
Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions. If you develop symptoms following exposure such as skin rash, you should seek medical advice immediately and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
Accidental ingestion may result in gastrointestinal disturbances. In order to reduce the risk of accidental ingestion by children, do not take the tablets out of the blister until ready to administer to the animal. Return part-used tablets into the blister and carton and use at the subsequent administration.
In case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not smoke, eat or drink while handling the medication.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Allergic reaction Nausea, Vomiting, Diarrhoea

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product in dogs has not been established during pregnancy and lactation.

Pregnancy and lactation:
Cephalosporins cross the placenta. Laboratory studies in animals have not produced any evidence of teratogenic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

In order to ensure efficacy, the veterinary medicinal product should not be used in combination with bacteriostatic antibiotics. Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance nephrotoxicity risks.
See section 3.5 “Special precautions for safe use in target species”.

3.9 Administration routes and dosage

Oral use.

Dose: 20 mg cefadroxil/kg body weight per day (equivalent to 1/4 tablet per 12.5 kg body weight) administered once daily. The veterinary medicinal product should be administered with food.
In order to avoid under-dosing, the veterinarian should prescribe a sufficient number of tablets to ensure the animal receives at least 20 mg cefadroxil per kg bodyweight per day for the duration of the intended treatment period.
The duration of treatment depends on the nature and severity of the infection and on the response.
Infections of soft tissues and urinary tract: 10 days; pyoderma and severe infections of urinary tract may require a longer treatment period, up to 3 months.
The treatment should last at least 48 hours after the disappearance of the symptoms.
To ensure a correct dosage, body weight should be determined as accurately as possible.
For dogs over 12.5 kg. The smaller tablet size should be used to achieve accurate dosing in dogs weighing less than 12.5 kg.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No other known side effects than those under section 3.6.
In the event of overdose, treatment should be symptomatic.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01DB05

4.2 Pharmacodynamics

Cefadroxil is a broad spectrum semisynthetic beta-lactam antibacterial, belonging to the family of first-generation cephalosporins.

Cefadroxil acts by inhibiting the synthesis of the bacterial cell wall by binding to PBP (penicillin binding proteins), interfering with the final phase of peptidoglycan synthesis.
Its spectrum of activity includes *Staphylococci* (including strains producing penicillinases), S*treptococci*, *Escherichia coli*, *Klebsiella* spp., *Proteus mirabilis* and *Pasteurella multocida*.
Cefadroxil is not active against MRSA (Methicillin-resistant *Staphylococcus aureus*).

In the absence of specific breakpoints for cefadroxil, the following breakpoints were established by CLSI for cephalexin (1st generation cephalosporin):
- Urinary tract infections in dogs caused by *E. coli*, *K. pneumonia*, *P. mirabilis*: S: ≤ 16 µg/ml, R: ≥ 32 µg/ml

Source: CLSI VET08, 4th ed. (2018).

Resistance to cephalosporins can be due to one of the following mechanisms of resistance. Firstly, the production of cephalosporinases, that inactivate the antibiotic by hydrolysis of the β-lactam ring, is the most prevalent mechanism among Gram-negative bacteria. This resistance is transmitted by plasmid or chromosomally. Secondly, a decreased affinity of the PBPs (penicillin-binding proteins) for beta-lactam drugs is frequently involved for beta-lactam resistant Gram-positive bacteria. Lastly, efflux pumps, extruding the antibiotic from the bacterial cell, and structural changes in porins, reducing passive diffusion of the drug through the cell wall, may contribute to the resistant phenotype of a bacterium.
Well-known cross-resistance (involving the same resistance mechanism) exists between antibiotics belonging to the beta-lactam group due to structural similarities. It occurs as a result of the expression of beta-lactamases enzymes, structural changes in porins or in presence of efflux pumps. Co-resistance (different resistance mechanisms involved) has been described in *E.coli* due to a plasmid harbouring various resistance genes.

4.3 Pharmacokinetics

After the oral administration of the veterinary medicinal product to dogs, cefadroxil is rapidly absorbed reaching a maximum plasma concentration of approximately 20 µg/ml within 1-3 hours post-administration. Cefadroxil is excreted rapidly and completely in the urine.
An administration of 20 mg/kg bw/day for 10 days does not produce accumulation of the active substance.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life of divided tablets: 3 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Keep every part of the divided tablet in the blister and use at time of next administration.

5.4 Nature and composition of immediate packaging

PVC/PE/PVdC/PE/PVC blisters sealed with thermoheated aluminium foil packaged into a cardboard box.

Pack-sizes:
Cardboard box with 1 blister containing 6 tablets

Cardboard box with 10 blisters containing 6 tablets (60 tablets)

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

FATRO S.p.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10836/006/002

8. DATE OF FIRST AUTHORISATION

28/06/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

05/12/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).