B. PACKAGE LEAFLET

PACKAGE LEAFLET

SEMELCEF 200 mg tablets for dogs and cats (AT, BE, CY, CZ, EE, EL, ES, HR, HU, IE, PL, PT, SI, SK)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
SUPPORT PHARMA, S.L., General Alvarez de Castro, 39 - 28010 Madrid, Spain.

Manufacturer responsible for batch release:
FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia (BO), Italia.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEMELCEF 200 mg tablets for dogs and cats
Cefadroxil as monohydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Each tablet contains:
Active substance:
Cefadroxil 200 mg (equivalent to Cefadroxil monohydrate 210 mg).

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

4. INDICATIONS

Treatment of the following infections in dogs and cats:

- 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.

5. 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.

6. ADVERSE REACTIONS

Allergic reactions to cephalosporins may occur in very rare cases.
Nausea, vomiting and/or diarrhea may occur in very rare cases.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Oral use.
Dose: 20 mg cefadroxil/kg body weight per day (equivalent to 1/4 tablet per 2.5 kg body weight) administered once daily. The 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.
The weight of the animals should be determined as accurately as possible to avoid underdosing. Use of this veterinary medicinal product in cats and dogs weighing less than 2.5 kg should be based on a careful benefit: risk assessment by the responsible veterinarian. See section 12.

9. ADVICE ON CORRECT ADMINISTRATION

The weight of the animals should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
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.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after EXP.. The expiry date refers to the last day of that month.
Shelf-life of the divided tablet after first use of the primary packaging: 3 days.

12. SPECIAL WARNINGS

Special warnings for each target species
Pyoderma is usually secondary to an underlying disease. It is advisable to determine the underlying disease to ensure the appropriate treatment is administered.

Special precaution for use in animals
Use of the 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 product is used.
Use of the 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 product should be administered with caution. Antimicrobials known to be nephrotoxic should not be administered concurrently and the product should be used only according to a risk/benefit assessment by the responsible veterinarian.

The product is not appropriate for animals weighing less than 2.5 kg. In these animals, the product should be used according to the benefit-risk assessment performed by the responsible veterinarian.

Special precautions to be taken by 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.
Do not handle this veterinary medicinal product if you know you are sensitised or if you have been advised not to be in contact with such substances.
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 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.

Use during pregnancy, lactation or lay
Cephalosporins cross the placenta. However, studies conducted in laboratory animals with cefadroxil have not produced any evidence of teratogenic effects. The safety of the veterinary medicinal product in dogs and cats has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

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.
And see section 12, Special precautions for use in animals

Overdose
No other known side effects than those under section 6. In the event of overdose, treatment should be symptomatic.

Incompatibilities
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack - sizes:
- Box with 1 blister containing 10 tablets
- Box with 10 blisters containing 10 tablets (100 tablets)

Not all pack sizes may be marketed.