SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PETALEXIN 300 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:
- Active substance
Cefalexin ……..300 mg
(as Cefalexin Monohydrate)

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
Creamy oblong tablet with small brown spots marked with a score-line.
The tablets can be divided into halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the treatment of bacterial skin infections in dogs (including deep and superficial pyodermas) caused by organisms susceptible to Cefalexin.
For the treatment of urinary-tract infections in dogs (including nephritis and cystitis) caused by organisms susceptible to Cefalexin.

4.3 Contra-indications

Do not use in animals known to be hypersensitive to penicillins and cephalosporins.
Do not use in rabbits, guinea pigs, hamsters and gerbils.
Do not use in known cases of hypersensitivity to the active substance, to other cephalosporins, to other substances of the β-lactam group or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

As with other antibiotics which are excreted mainly by the kidneys, unnecessary accumulation may occur in the body when renal function is impaired. In case of known renal insufficiency, the dose should be reduced and antimicrobials known to be nephrotoxic should not be administered concurrently.
This product should not be used to treat puppies of less than 1 kg of bodyweight.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to Cefalexin and may decrease the effectiveness of treatment with penicillins due to the potential for cross-resistance.

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, national and regional antimicrobial policies should be taken into account when the product is used.

As the tablets are palatable to animals there is a danger of excessive ingestion. The tablets must therefore be stored out of the reach of animals.

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 sensitivity to cephalosporin and *vice versa*. Allergic reactions to these substances may occasionally be serious.

1- Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

2- Handle this product with great care to avoid exposure, taking all recommended precautions. Take care to avoid prolonged skin contact. Wash hands after use.

3- 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 with breathing are more-serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity to Cefalexin is rare, however, the product should not be administered to animals which are known to be hypersensitive to Cefalexin or penicillins. Refer also to section 4.3.
Allergic cross-reactivity with other β-lactam may occur.

Very rare cases of soft faeces and vomiting may be observed in animals during treatment.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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).

4.7 Use during pregnancy and lactation

This product can be used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

The association of first-generation cephalosporins with aminoglycoside antibiotics and some diuretics such as furosemide can enhance nephrotoxicity risks.
The bactericidal activity of cephalosporins is reduced by concomitant administration of bacteriostatic acting compounds (tetracyclines, chloramphenicol, macrolides and rifampicin).

4.9 Amounts to be administered and administration route

15 mg of Cefalexin per kg of bodyweight twice daily (equivalent to 30 mg per kg of bodyweight per day) for a duration of:
- 14 days in case of urinary-tract infection in dogs;
- at least 15 days in case of superficial infectious dermatitis in dogs;
- at least 28 days in case of deep infectious dermatitis in dogs.

To achieve this dosage, administer:
<u>in dogs:</u>
- Twice daily, one tablet per 20 kg of bodyweight or ½ tablet per 10 kg of bodyweight.
  To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

Due to its palatable formulation, the product is well accepted by dogs but may be crushed or added to food if necessary.
In severe or acute conditions, the dose may be safely doubled.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Trials performed on animals with up to 5 times the recommended dose of 15 mg/kg demonstrated that the product is well tolerated.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use, first generation cephalosporins.
ATCvet code: QJ01DB01.

5.1 Pharmacodynamic properties

Cefalexin acts by inhibiting the nucleopeptide synthesis of the bacterial wall. Cephalosporins interfere with the enzymes of transpepditation making it unable to cross-link the peptidoglycans of the bacterial cell wall. The glycan cross-linking is essential for the cell to build its cell wall. Inhibition of the biosynthesis results to a weakened cell wall, which eventually ruptures to osmotic pressure. The combined action results in cell lysis and filament formation.
Cefalexin is active against a wide range of gram-positive and gram-negative bacteria: *Staphylococcus* spp. (including penicillin-resistant strains), *Streptococcus* spp., *Escherichia coli*, *Klebsiella* spp. and *Salmonella* spp.. Cefalexin is not inactivated by β-lactamases produced by gram-positive bacteria and which usually affect penicillins.

5.2 Pharmacokinetic particulars

After single oral administration of the recommended dosage of 15 mg of Cefalexin per kg of bodyweight to Beagle dogs, plasma concentrations were observed within 30 minutes. The plasma peak was observed at 1.3 hour with a plasma concentration of 18.2 µg/ml.
The bioavailability of the active was over 90 %. Cefalexin was detected until 24 hours after the administration. The first urine specimen was collected within 2 to 12 hours with peak concentrations of Cefalexin measured at 430 to 2758 µg/ml within 12 hours.

After repeated oral administration of the same dosage, twice a day for 7 days, plasma peaks occurred 2 hours later with a concentration of 20 µg/ml. Over the treatment period, concentrations were maintained above 1 µg/ml. The mean elimination half-life is 2 hours. Skin levels were around 5.8 to 6.6 µg/g, 2 hours after treatment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Crospovidone
- Mannitol
- Starch pregelatinised
- Croscarmellose sodium
- Colloidal anhydrous silica
- Colloidal hydrated silica
- Povidone K30
- Microcrystalline cellulose (type A)
- Poultry liver powder

- Magnesium stearate
- Microcrystalline cellulose (type B)

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precaution for storage

Keep the blisters in the outer carton.
Divided tablets should be stored in blister packs.

6.5 Nature and composition of immediate packaging

Blister packs consisting of cold formed OPA/Al/PVC foil and aluminium foil.

Cardboard Box with 30 blisters of 7 tablets.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Alfamed
13ème rue - L.I.D
Carros Cedex
06517
France

8. MARKETING AUTHORISATION NUMBER

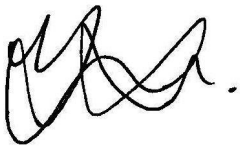
Vm 17902/4102

9. DATE OF FIRST AUTHORISATION

15 January 2018

10. DATE OF REVISION OF THE TEXT

October 2022



Approved: 05 October 2022