ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box with 30 blisters of 7 tablets.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PETALEXIN 75 mg tablets for dogs and cats
Cefalexin

2. STATEMENT OF ACTIVE SUBSTANCE

One tablet contains:

Active substance:

Cefalexin	75 mg
(as Cefalexin Monohydrate)	

3. PHARMACEUTICAL FORM

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

4. PACKAGE SIZE

Cardboard Box with 30 blisters of 7 tablets.

5. TARGET SPECIES

Cats and Dogs

6. INDICATIONS

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

7. METHOD AND ROUTE OF ADMINISTRATION

15 mg of Cefalexin per kg of bodyweight twice daily (equivalent to 30 mg per kg of bodyweight per day) for a duration of:

- 5 days in case of cutaneous and subcutaneous infections (wounds and abscesses) in cats;
- 14 days in case of urinary-tract infection in cats and 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:
In cats and dogs

- Twice daily, one tablet per 5 kg of bodyweight or ½ tablet per 2.5 kg of bodyweight.

To ensure correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
Due to its palatable formulation, the product is well accepted by cats and dogs but may be crushed or added to food if necessary.
In severe or acute conditions, the dose may be safely doubled.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for full user warnings.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the blisters in the outer carton in order to protect from light.
Divided tablets should be stored in blister packs.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 17902/4101

17. MANUFACTURER’S BATCH NUMBER

Batch: {number}

Distributor: CVS House, Owen Road, Diss, Norfolk, IP22 4ER - UK

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister 75mg

NAME OF THE VETERINARY MEDICINAL PRODUCT
PETALEXIN 75 mg Tablets for dogs and cats
(cefalexin monohydrate)

NAME OF THE MARKETING AUTHORISATION HOLDER
ALFAMED

THE WORDS "FOR ANIMAL TREATMENT ONLY"
For animal treatment only

EXPIRY DATE
EXP: {month/year}

BATCH NUMBER
Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

Marketing Authorisation Holder and manufacturer responsible for batch release
Alfamed
13ème rue - L.I.D
Carros Cedex
06517
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PETALEXIN 75 mg Tablets for dogs and cats
PETALEXIN 300 mg Tablets for dogs
PETALEXIN 600 mg Tablets for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One tablet contains Cefalexin (as Cefalexin Monohydrate):

PETALEXIN 75 mg Tablets for dogs and cats	75 mg
PETALEXIN 300 mg Tablets for dogs	300 mg
PETALEXIN 600 mg Tablets for dogs	600 mg

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

4. INDICATIONS

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

5. CONTRAINDICATIONS

Do not use in animals which are 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.

6. ADVERSE REACTIONS

Very rare cases of soft faeces and vomiting may be observed in animals during treatment.
Hypersensitivity to Cefalexin is rare, however, the product should not be administered to animals which are known to be hypersensitive to Cefalexin or penicillin
Allergic cross-reactivity with other β-lactams may occur.
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).

7. TARGET SPECIES

Cats and Dogs

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

15 mg of Cefalexin per kg of bodyweight twice daily (equivalent to 30 mg per kg of bodyweight per day) for a duration of:
- 5 days in case of cutaneous and subcutaneous infections (wounds and abscesses) in cats;
- 14 days in case of urinary-tract infection in cats and 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:
PETALEXIN 75 mg Tablets for dogs and cats:
Twice daily, one tablet per 5 kg of bodyweight or ½ tablet per 2.5 kg of bodyweight.
PETALEXIN 300 mg Tablets for dogs:
Twice daily, one tablet per 20 kg of bodyweight or ½ tablet per 10 kg of bodyweight.
PETALEXIN 600 mg Tablets for dogs:
Twice daily, one tablet per 40 kg of bodyweight or ½ tablet per 20 kg of bodyweight.
To ensure correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep the blisters in the outer carton.
Divided tablets should be stored in blister packs.
Keep out of the sight and reach of children

12. SPECIAL WARNINGS

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 or kittens under 9 weeks of age.

Use of the product deviating from the instructions given in section “Dosage for each species, route and method of administration”, may increase the prevalence of bacteria resistant to Cefalexin and may decrease the effectiveness of treatment with other cephalosporins and 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.

Local treatment of cutaneous and subcutaneous infections in cats should be considered as a complement of the antibiotic treatment.

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.

Pregnancy and lactation:
The product can be used in pregnant and lactating animals.

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).

Overdose (symptoms, emergency procedures, antidotes):
Trials performed on animals with up to 5 times the recommended dose of 15 mg/kg demonstrated that the product is well tolerated.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{month/year}

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription. Pack size of 210 tablets.

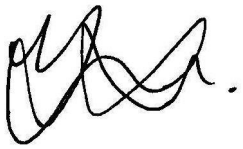
Cardboard Box with 30 blisters of 7 tablets.

POM-V

PETALEXIN 75 mg Tablets for dogs and cats
Vm 17902/ 4101
PETALEXIN 300 mg Tablets for dogs
Vm 17902/4102

PETALEXIN 600 mg Tablets for dogs
Vm 17902/4103

Distributor: CVS House, Owen Road, Diss, Norfolk, IP22 4ER - UK



Approved: 06 October 2022