ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefaseptin 750 mg tablets for dogs
cefalexin

2. STATEMENT OF ACTIVE SUBSTANCES

cefalexin (as cefalexin monohydrate)…… 750 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

6, 12, 72 and 150 tablets.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

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

Store in the original package.
Shelf life after first opening the immediate packaging: 48 hours.
Return any part used tablet to the opened blister-pack.

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

Disposal: read package leaflet.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4143

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefaseptin 750 mg tablets for dogs
cefalexin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Cefaseptin 750 mg tablets for dogs

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

Marketing authorisation holder:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release:
VETOQUINOL
MAGNY-VERNOIS
F-70200 LURE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefaseptin 750 mg tablets for dogs
cefalexin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One tablet contains:

cefalexin (as cefalexin monohydrate)…… 750 mg

Beige oblong tablet.
The tablet can be divided into 2 or 4 equal parts.

4. INDICATION(S)

For the treatment of bacterial skin infections (including deep and superficial pyoderma) caused by organisms, including *Staphylococcus* spp., susceptible to cefalexin.

For the treatment of urinary-tract infections (including nephritis and cystitis) caused by organisms, including *Escherichia coli,* susceptible to cefalexin.

5. CONTRAINDICATIONS

Do not use in cases of known 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 known cases of resistance to cephalosporins or penicillins.

Do not use in rabbits, guinea pigs, hamsters and gerbils.

6. ADVERSE REACTIONS

In rare cases hypersensitivity can occur.
In cases of hypersensitivity reactions the treatment should be stopped.
In very rare cases, nausea, vomiting and/or diarrhoea have been observed in some dogs after administration.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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

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

Oral use.
15 mg of cefalexin per kg of bodyweight twice daily (equivalent to 30 mg per kg of bodyweight per day) corresponding to one tablet per 50 kg of bodyweight twice daily.

Dogs:
Urinary-tract infection: 14 days
Superficial bacterial infection of the skin: At least 15 days
Deep bacterial infection of the skin: At least 28 days

This product should not be used to treat puppies of less than 1 kg of bodyweight.

The product may be crushed or added to food if necessary.

In severe or acute conditions, except in cases of known renal insufficiency (see Special precautions for use in animals), the veterinarian can decide that the dose may be doubled. Always follow prescribed dose.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure the correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original package.
Shelf life after first opening the immediate packaging: 48 hours.
Return any part used tablet to the opened blister-pack.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
The need for systemic antibiotics compared with non-antibiotic alternatives for the treatment of superficial pyoderma should be carefully considered by the responsible veterinarian.
As with other antibiotics which are excreted mainly by the kidneys, accumulation of the drug in the body may occur 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 should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about the susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Pseudomonas aeruginosa is known for intrinsic (or natural) resistance to cefalexin.

The tablets are flavoured (presence of porcine liver powder). In order to avoid accidental ingestion, store tablets out of reach of the animals.

The product should be used according to the instructions in this package leaflet, and those given by the dispensing veterinarian, in order to help prevent the development of bacteria resistant to cefalexin and reduced effectiveness of treatment that can arise as a result.

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 penicillins may lead to cross-reactions 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. Wash hands after use.
3. If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty in breathing are more-serious symptoms and require urgent medical attention.

Use during pregnancy, lactation or lay:
The safety of the veterinary medicinal product has not been established in bitches during pregnancy and lactation.
Laboratory studies have not produced any evidence of teratogenic effects in mice (up to 400 mg cefalexin/kg bw/day) and rats (up to 1200 mg cefalexin/kg bw/day). In mice, maternal effects and foetotoxicity were observed from the lowest dose tested (100 mg cefalexin/kg bw/day). In rats, there is evidence of foetotoxicity at 500 mg cefalexin/kg bw/day and maternal effects from the lowest dose tested (300 mg cefalexin/kg bw/day).
Use only in accordance with 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 (macrolides, sulfonamides and tetracyclines). Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance nephrotoxicity risks.
Concomitant use with such active substances should be avoided.

Overdose (symptoms, emergency procedures, antidotes):
Studies on animals with up to 5 times the recommended twice daily dosage of 15 mg cefalexin/kg have been performed.

Adverse reactions that may occur at the recommended dose (nausea, vomiting, and/or diarrhea) are expected in the case of overdose. In the event of overdose, treatment should be symptomatic.

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

Any unused veterinary medicinal product 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

August 2020

15. OTHER INFORMATION

PVC/aluminium/OPA – PVC blister
Cardboard box of 1 blister of 6 tablets
Cardboard box of 2 blisters of 6 tablets
Cardboard box of 12 blisters of 6 tablets
Cardboard box of 25 blisters of 6 tablets

Not all pack sizes may be marketed.

For any information about this Veterinary Medicinal Product, please contact the local representative of the Marketing Authorisation Holder.

Approved 26 November 2020