ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 75 mg Chewable Tablets for Cats

Cefalexin (as cefalexin monohydrate)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 250 mg tablet contains:
Cefalexin (as cefalexin monohydrate) .....75 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

Cardboard box with 1 blister of 10 tablets
Cardboard box with 2 blisters of 10 tablets
Cardboard box with 10 blisters of 10 tablets
Cardboard box with 15 blisters of 10 tablets
Cardboard box with 20 blisters of 10 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C
Read the package leaflet before use.

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/3039

17. MANUFACTURER'S BATCH NUMBER

Batch:

Veterinary Medicinal product

Therios 75 mg Chewable Tablets for Cats

PART IB

A – LABELLING – BLISTER

Pharmaceutical form

Chewable Tablet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 75 mg Chewable Tablets for Cats

Cefalexin (as cefalexin monohydrate)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva logo

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:

Therios 75 mg Chewable Tablets for Cats

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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 75 mg Chewable Tablets for Cats

Cefalexin (as cefalexin monohydrate)

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

Each 250 mg tablet contains
Cefalexin (as cefalexin monohydrate) .....75 mg
Chewable tablet
Oblong scored beige tablet. The tablets can be divided into equal parts

4. INDICATION(S)

In cats :
Infections caused by bacteria susceptible to cefalexin
. Lower urinary tract infections due to *E.coli* and *Proteus mirabilis,*
.Treatment of cutaneous and subcutaneous infections: pyoderma due to *Staphylococcus.spp* and wounds and abscesses due to *Pasteurella spp*.

5. CONTRAINDICATIONS

Do not use in case of severe kidney failure

Do not use in animals which are known to be hypersensitive to cephalosporins or to any other substance of the b-lactam group.
Do not use in rabbits, guinea pigs, hamsters, gerbils and other small rodents.

6. ADVERSE REACTIONS

Vomiting and/or diarrhoea have been observed.

Allergic reactions are possible with cefalexin and allergic cross-reactivity with other β-lactams may occur.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

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

Oral use
15 mg cefalexin per kg bodyweight twice daily, equivalent to 1 tablet for 5 kg bodyweight for:
- 5 days for wounds and abscesses
- 10 to 14 days in case of urinary tract infections,
- 14 days at least in case of pyoderma. The treatment must be continued for 10 days once the lesions have disappeared.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing
In case of use of half tablets: put the remaining quantity of the tablet back into the blister pocket and use it for the next administration.

9. ADVICE ON CORRECT ADMINISTRATION

The tablets are flavoured. They can be administered with food or directly into the mouth of the animal.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C
Store in the original package
Return any halved tablet to the opened blister pack
Any divided tablet portions remaining after 24 hours should be discarded
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after ‘EXP’. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

i) Special precautions for use in animals

As with other antibiotics which are excreted mainly by the kidneys, systemic accumulation may occur when renal function is impaired. In cases of known renal insufficiency, the dose should be reduced and/or the interval of administration increased and nephrotoxic drugs should not be administered concurrently.
Wherever possible, the use of the product should be based on susceptibility testing.
Official and local antimicrobial policies on antibiotherapy 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 the cefalexin and may decrease the effectiveness of treatment with penicillins due to the potential for cross resistance
This product should not be used to treat kittens less than 9 weeks of age.
The use of the product in cats weighing less than 2.5 kg should be in accordance with the benefit/risk assessment performed by the responsible veterinarian.
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

ii) 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 cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

- Do not handle this product if you know you are sensitised, or if you have been advised not to be in contact with such substances.
- Handle this product with great care to avoid exposure taking all recommended precautions. Wash hands after use.
- 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 in breathing are more serious symptoms and require urgent medical attention.
- In case of accidental ingestion, seek medical attention and show the package leaflet or the label to the doctor.

Use during pregnancy, lactation or lay

Laboratory studies in mouse, rat and rabbit have not produced any evidence of teratogenic effects. The safety of the product has not been investigated in pregnant or lactating cats and should only be used according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

The bactericidal activity of cephalosporins is reduced by concomitant administration of bacteriostatic acting compounds (macrolides, sulfonamides and tetracyclines).
Nephrotoxicity can be increased when 1st generation cephalosporins are combined with polypeptide antibiotics, aminoglycosides or some diuretics (furosemide).
Concomitant use with such active substances should be avoided.

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

October 2022

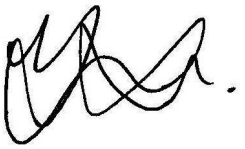
15. OTHER INFORMATION

Pack sizes:
Cardboard box with 1 blister of 10 tablets
Cardboard box with 2 blisters of 10 tablets
Cardboard box with 10 blisters of 10 tablets
Cardboard box with 15 blisters of 10 tablets
Cardboard box with 20 blisters of 10 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.

Local representative:



Approved: 06 October 2022