Veterinary Medicinal Product

Therios 750 mg palatable tablets for dogs

PART I B

A – LABELLING "OUTER PACKAGE"

Pharmaceutical Form

Tablet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 750 mg palatable tablets for dogs
Cefalexin (as cefalexin monohydrate)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Cefalexin (as cefalexin monohydrate) .....750 mg

3. PHARMACEUTICAL FORM

Tablet
Round scored beige palatable tablet
The tablet can be divided into halves and quarters

4. PACKAGE SIZE

10 tablets
30 tablets
200 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

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: mm/yyyy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Divided tablets should be stored in the blister pack. Any divided tablet portions remaining after 48 hours should be discarded.

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 REACH AND SIGHT 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(S)

Vm 15052/4120

17. MANUFACTURER'S BATCH NUMBER

Batch:

Veterinary Medicinal Product

Therios 750 mg palatable tablets for dogs

PART I B

A – LABELLING "BLISTER"

Pharmaceutical Form

Tablet

The aluminium foil is printed with the following mentions: refer to the points 1 – 2 - 5.

The batch number and the expiry date (month/year) are printed on the blister pack (PVC side): refer to the points 3 – 4.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 750 mg palatable tablets for dogs
Cefalexin (as cefalexin monohydrate)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva logo

3. EXPIRY DATE

EXP: mm/yyyy

4. BATCH NUMBER

Batch:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

Veterinary Medicinal Product

Therios 300 mg palatable tablets for dogs

Therios 750 mg palatable tablets for dogs

PART I B

B. PACKAGE LEAFLET

Pharmaceutical Form

Tablet

PACKAGE LEAFLET

Therios 300 mg palatable tablets for dogs

Therios 750 mg palatable 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:
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 300 mg palatable tablets for dogs
Cefalexin (as cefalexin monohydrate)

Therios 750 mg palatable tablets for dogs
Cefalexin (as cefalexin monohydrate)

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

THERIOS 300
Each tablet contains:
Cefalexin (as cefalexin monohydrate) .....300 mg

THERIOS 750
Each tablet contains:
Cefalexin (as cefalexin monohydrate) .....750 mg

Round scored beige palatable tablet
The tablet can be divided into halves and quarters

4. INDICATION(S)

For the treatment of bacterial skin infections in dogs (including deep and superficial pyoderma) caused by organisms sensitive to cefalexin.
For the treatment of urinary tract infections in dogs (including nephritis and cystitis) caused by organisms sensitive to cefalexin.

5. CONTRAINDICATIONS

Do not use in animals which are known to be hypersensitive to penicillins, cephalosporins or any of the excipients
Do not use in case of severe renal failure
Do not use in rabbits, guinea pigs, hamsters and gerbils.

6. ADVERSE REACTIONS

Vomiting and diarrhoea have been observed in dogs. In rare cases hypersensitivity can occur.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

For oral administration
15 mg cefalexin per kg bodyweight twice daily (equivalent to 30 mg per kg bodyweight per day) for duration of:
- 14 days in cases of urinary tract infection
- At least 15 days in cases of superficial infectious dermatitis
- At least 28 days in cases of deep infectious dermatitis

In severe or acute conditions the dose may be safely doubled to 30 mg/kg twice daily. To allow for accuracy of dosing, tablets can be halved or quartered.

Any increase in the dose or duration of treatment should be according to a risk/benefit assessment by the prescribing veterinarian.

To ensure a correct dosage bodyweight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

Therios tablets are well accepted by dogs but may be crushed or added to a small quantity of food immediately prior to feeding if necessary.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C.
Keep the blister in the outer carton.
Shelf-life after first opening the immediate packaging: 48 hours
Divided tablets should be stored in the blister pack. Any divided tablet portions remaining after 48 hours should be discarded.
Do not use the veterinary medicinal product after the expiry date stated on the blister and outer carton after EXP. The expiry date refers to the last day of that month

12. SPECIAL WARNING(S)

Special precautions for use in animals
Wherever possible, the use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.
As with other antibiotics which are excreted mainly by the kidneys, systemic accumulation may occur when renal function is impaired. In case of known renal insufficiency the dose should be reduced.
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 other beta-lactam antibiotics due to the potential for cross-resistance.

Safety of the excipient, ammonium glycyrrhizate, has not been established in dogs less than 1 year old.
The product is not recommended for use in dogs less than 2.5 kg bodyweight for THERIOS 300 and 6 kg bodyweight for THERIOS 750.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Cephalosporins may cause sensitization (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillins 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. 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. Swellings of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

In the event of accidental ingestion, particularly by a child, seek medial attention and show the doctor the leaflet

Use during pregnancy, lactation or lay
Do not use in pregnant or lactating bitches.

Interaction with other medicinal products and other forms of interaction
In order to ensure efficacy, the 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

Overdose (symptoms, emergency procedures, antidotes), if necessary
Trials performed on animals with up to 5 times the recommended dosage 15 mg/kg demonstrated that cefalexin was well tolerated.

Incompatibilities
Not applicable

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 20 blisters of 10 tablets
Cardboard box with 3 blisters of 10 tablets (Therios 750 mg palatable tablets for dogs only)

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 07 October 2022