

**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 medical 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

