PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 10, 30 or 200 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 750 mg palatable tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PACKAGE SIZE

10 tablets
30 tablets
200 tablets

4. TARGET SPECIES

Dog

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP: mm/yyyy

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5071

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 750

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

750 mg of Cefalexin (as cefalexin monohydrate)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP: mm/yyyy

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 300 mg palatable tablets for dogs

Therios 750 mg palatable tablets for dogs

2. COMPOSITION

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

3. TARGET SPECIES

Dog

4. INDICATIONS FOR USE

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 cases of hypersensitivity to penicillins, cephalosporins, or to any of the excipients.

Do not use in case of severe renal failure
Do not use in rabbits, guinea pigs, hamsters and gerbils.

6. SPECIAL WARNINGS

Special precautions for use in animals
Whenever possible, the use of the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 sensitisation (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. People with known hypersensitivity to cephalosporins should avoid contact with the veterinary medicinal product.
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 case of accidental ingestion, particularly by a child, seek medical advice and show the package leaflet or the label to the physician.

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 twice daily dosage of 15 mg/kg demonstrated that cefalexin was well tolerated.

7. ADVERSE EVENTS

Dog

Rare (1 to 10 animals/10,000 animals treated):
Hypersensitivity reaction
Undetermined frequency (cannot be estimated from the available data):
Vomiting, Diarrhoea

Reporting adverse events is important. It allows continuous safety monitoring of a

product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Oral use.

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 .

9. ADVICE ON CORRECT ADMINISTRATION

The veterinary medicinal product 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 PERIODS

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 PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/5069
Vm 14966/5071

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

01628 334056
technicalandpvuk-group@ceva.com

Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière 53950 LOUVERNE FRANCE

17. OTHER INFORMATION

Gavin Hall

Approved: 04 November 2025