ANNEX II

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 10 or 200 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 300 mg palatable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

10 tablets
200 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTE(S) 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.

User Warnings
Penicillins and cephalosporins may occasionally cause severe allergic reactions.
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 NUMBER(S)

Vm 14966/3068

15. BATCH NUMBER

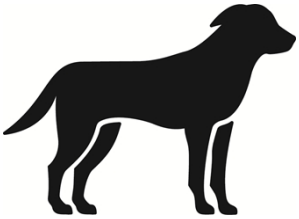
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

cefalexin 300 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

Dogs.

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 safe use in the target species:
Wherever 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 veterinary medicinal 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 case of accidental ingestion, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy, lactation or lay:
Do not use during pregnancy and lactation.

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.
Concurrent use of first generation cephalosporins with aminoglycoside antibiotics or some diuretics such as furosemide can enhance nephrotoxicity risks

Overdose:
Trials performed on animals with up to 5 times the recommended dosage 15 mg/kg demonstrated that cefalexin was well tolerated.

7. Adverse events

Dogs:

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 veterinary medicinal 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.

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 or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database.

14. Marketing authorization numbers and pack sizes

Vm 14966/3068
Vm 14966/3070

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

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 Louverné
France

17. Other information

Gavin Hall

Approved: 04 November 2025