PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 10, 20, 100, 150 or 200 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 75 mg Chewable Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. 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

4. TARGET SPECIES

Cat

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

EXP {month/year}
Any divided tablet portions remaining after 24 hours should be discarded.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C
Store in the original package.
Return any halved tablet to the opened blister pack.

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 NUMBER

Vm 14966/5070

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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 medicine subject to prescription

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

75 mg of Cefalexin (as cefalexin monohydrate)

3. BATCH NUMBER

Lot: {number}

4. EXPIRY DATE

EXP {month/year}

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 75 mg Chewable Tablets for Cats

2. COMPOSITION

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

Oblong scored beige tablet. The tablets can be divided into two equal parts

3. TARGET SPECIES

Cats

4. INDICATIONS FOR USE

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

Do not use in rabbits, guinea pigs, hamsters, gerbils and other small rodents.

6. SPECIAL WARNINGS

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 veterinary medicinal product should be based on susceptibility testing.

Official and local antimicrobial policies on antibiotherapy should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal 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 veterinary medicinal product should not be used to treat kittens less than 9 weeks of age.
Use of the veterinary medicinal 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.

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.

Special precautions for the protection of the environment
Not applicable

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.

7. ADVERSE EVENTS

Cat

Undetermined frequency (cannot be estimated from the available data):	Vomiting[1], Diarrhoea[1]

[1]In case of recurring vomiting and/or diarrhoea, the treatment should be discontinued, and the advice of the attending veterinarian sought.

Allergic reactions are possible with cefalexin and allergic cross-reactivity with other beta lactams may occur.

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.

8. DOSAGE FOR EACH SPECIES, ROUTES 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.

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 PERIODS

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 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 14966/5070

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.

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