SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 75 mg Chewable Tablets for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s):
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Cat

4.2 Indications for use, specifying the target species

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*.

4.3 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.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

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

4.6 Adverse reactions (frequency and seriousness)

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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system.
See also the package leaflet for respective contact details.

4.7 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.

4.8 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.

4.9 Amount(s) to be administered and administration route

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.

The tablets are flavoured. They can be administered with food or directly into the mouth of the animal.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICALPROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use, first generation cephalosporin

ATCvet code: QJ01DB01

5.1 Pharmacodynamic properties

Cefalexin monohydrate is a bactericidal antibiotic of the cephalosporin family, obtained by hemi-synthesis of the 7-amino cephalosporanic nucleus.
Cefalexin acts by inhibiting the nucleopeptide synthesis of the bacterial wall.

Cephalosporins interfere with transpeptidation by acylating the enzyme making it unable to cross-link muramic acid-containing peptidoglycan strands. The inhibition of the biosynthesis of the material required to build the cell wall results in a defective cell wall and consequently osmotically unstable to protoplasts. The combined action results in cell lysis and filament formation. Cefalexin is active against Gram positive and Gram negative bacteria such as Staphylococcus spp (including penicillin-resistant strains), Streptococcus spp.,and Escherichia Coli. Cefalexin is not inactivated by β-lactamases produced by Gram positive bacteria. However, beta-lactamases produced by gram- negative bacteria can inhibit cefalexin by hydrolysis of the beta-lactam cycle.

Resistance to cefalexin may be due to one of the following mechanisms of resistance. Firstly, the production of various beta-lactamases (cephalosporinase), that inactivate the antibiotic, is the most prevalent mechanism among gram-negative bacteria. Secondly, a decreased affinity of the PBPs (penicillin-binding proteins) for beta-lactam drugs is frequently involved for beta -lactam resistant gram-positive bacteria. Lastly, efflux pumps, extruding the antibiotic from the bacterial cell, and structural changes in porins, reducing passive diffusion of the drug through the cell wall, may contribute to improve the resistant phenotype of a bacterium.

Well-known cross-resistance (involving the same resistance mechanism) exists between antibiotics belonging to the beta -lactam group due to structural similarities. It occurs with b-lactamases enzymes, structural changes in porins or variations in efflux pumps. Co-resistance (different resistance mechanisms involved) has been described in *E.coli* due to a plasmid harbouring various resistance genes.

MICs parameters available for *Staphylococcus* spp. and *Pasteurella multocida* are:

Staphylococcus spp	MIC_{50} 2 µg/ml	MIC_{90} 2 µg/ml
Pasteurella multocida	MIC_{50} 2 µg/ml	MIC_{90} 4 µg/ml

5.2 Pharmacokinetic particulars

In cats, the bioavailability after oral administration is around 56%.
In cats, after a single oral administration of 18.5 mg/kg of cefalexin, the plasmatic peak was reached after 1.6 h with a concentration of 22 µg/ml.
Cefalexin was detected in plasma till 24 hours after administration.
The diffusion of cefalexin in tissue is high. Cefalexin is mainly eliminated by urinary route (85%) under active form, urinary concentration peaks are significantly higher than plasmatic concentration peaks.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pig liver powder
Yeast
Croscarmellose sodium
Magnesium
stearateAnhydrous colloidal
silica
Calcium hydrogen phosphate dihydrate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
Polyvinylchloride / thermo-elast / polyvinylidene chloride – aluminium heat sealed blister: 3 years
Polyamide / aluminium / polyvinylchloride – aluminium heat sealed blister: 30 months

Any divided tablet portions remaining after 24 hours should be discarded

6.4 Special precautions for storage

Do not store above 25°C Store in

the original package.
Return any halved tablet to the opened blister pack.

6.5 Nature and composition of immediate packaging

Blister:

- Polyvinylchloride / thermo-elast / polyvinylidene chloride – aluminium heat sealed containing 10 tablets per blister
- Polyamide / aluminium / polyvinylchloride – aluminium heat sealed containing 10 tablets per blister

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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER

Vm 14966/5070

9. DATE OF FIRST AUTHORISATION

06 October 2010

10. DATE OF REVISION OF THE TEXT

November 2025

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 04 November 2025