

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Therios 300 mg Palatable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each 0.7g tablet contains:

Cefalexin (as cefalexin monohydrate).....300 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

Round scored beige tablet

The tablet can be divided into equal halves and quarters

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

Do not use in animals which are known to be hypersensitive to penicillins.

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

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 case of known renal insufficiency the dose should be reduced.

The product is not recommended for use in dogs less than 2.5 kg bodyweight.

Safety of the excipient, ammonium glycyrrhizate, has not been established in dogs less than 1 year old.

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 sensitized 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 medial attention and show the doctor the leaflet

4.6 Adverse reactions (frequency and seriousness)

Not applicable.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

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

To achieve this dose, administer according to the following table:

Dog's weight (kg)	Fractions of THERIOS 300 twice daily	Fractions of THERIOS 750 twice daily
2.5 - 4.9	¼	
5 - 9.9	½	
10 - 14.9	¾	
15 - 19.9	1	½
20 - 24.9	1+1/4	
25 - 29.9	1+1/2	¾

30 - 34.9	1+3/4	
35 - 39.9	2	1
40 - 49.9	-	
50 - 59.9		1+1/4
60 - 75		1+1/2

In severe or acute conditions the dose may be safely doubled to 30 mg/kg twice daily.

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.

4.10 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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Cefalexin monohydrate, the active ingredient of the Therios tablets, is a bactericidal antibiotic of the cephalosporin family, obtained by hemi-synthesis of the 7 amino-cephalosporanic nucleus.

ATCvet code: QJ01DB01

Pharmacotherapeutic group: Antibacterial for systemic use, first-generation cephalosporin

5.1 Pharmacodynamic properties

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 a wide range of Gram positive and Gram negative bacteria: *Staphylococcus spp* (including penicillin-resistant strains), *Streptococcus spp.*, *Pneumococcus spp.*, *Escherichia .coli*, *Klebsiella spp*, *Salmonella spp* and *Shigella spp*. Cefalexin is not inactivated by β -lactamases produced by Gram positive germs and which usually affect penicillins.

5.2 Pharmacokinetic particulars

After single oral administration of the recommended dosage of 15 mg cefalexin per kg bodyweight to Beagle dogs, plasma concentrations were observed within 30 minutes. The plasma peak was observed at 1.33 h with a plasma concentration of 21.2 μ g/ml. The bioavailability of the active was over 90%. Cefalexin was detected until 24 hours after the

administration. The first urine specimen was collected within 2 to 12 hours with peak concentrations of cefalexin measured at 430 to 2758 µg / ml within 12 hours. After repeated oral administration of the same dosage, twice a day for 7 days, plasma peaks occurred 2 hours later with a concentration of 20µg/ml. Over the treatment period concentrations were maintained above 1 µg/ml. The mean elimination half life is to 2 hours. Skin levels were around 5.8 to 6.6 µg /g 2 hours after treatment.

5.3 Environmental properties

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Croscarmellose sodium
Silica, colloidal anhydrous
Magnesium stearate
Yeast dried
Biscuit flavour F07012
Ammonium glycyrrhizate
Macrogol 6000

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 48 hours.

6.4. Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

Polyvinylchloride blister heat sealed with an aluminium cover foil.

Pack sizes:

Cardboard box with 1 blister 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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

Vm 20749/4004

9. DATE OF FIRST AUTHORISATION

27/02/2009

10 DATE OF REVISION OF THE TEXT

27/02/2009

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable