

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10966/018/002**

Case No: 7006599

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Vetoquinol UK Limited

Vetoquinol House, Great Slade, Buckingham MK18 1PA, United Kingdom

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Cefaseptin 600 mg film-coated tablets for dogs

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless revoked, shall continue in force from **15/04/2010**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefaseptin 600 mg film-coated tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active Substance

Cefalexin 600 mg

(as cefalexin monohydrate)

Excipient

Contains Titanium Dioxide (E171) as colouring agent 6.23 mg per tablet

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

White, oblong, biconvex film-coated tablets with a breaking notch.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

Canine pyoderma caused by *Staphylococcus intermedius*.

4.3 Contraindications

Do not use in animals with known hypersensitivity to cefalexin or penicillin.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Where renal insufficiency exists, the dose rate should be reduced. Where serious disturbances of the gastrointestinal tract occur, treatment should be discontinued.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

ii) 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.

1. Do not handle this product if you know you are sensitised, 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.
3. 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 breathing are more serious symptoms and require urgent medical attention.
4. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Mild diarrhoea, salivation and vomiting in rare cases.

Renal insufficiency requires a reduced dose rate as this condition influences plasma levels and overall distribution. Cefalexin may cause sensitisation (allergy).

4.7 Use during pregnancy, lactation or lay

No evidence of adverse effects (teratogenic or otherwise) have been seen in pregnant bitches or queens. The product should only be used where the clinical benefits outweigh the potential risks.

4.8 Interaction with other medicinal products and other forms of interaction

Cross-sensitisation and cross-resistance may exist between penicillins and cephalosporins.

4.9 Amounts to be administered and administration route

25 mg/kg body weight orally, twice daily for up to 3 weeks

Dogs of 12 kg bw: ½ tablet twice daily

Dogs of 24 kg bw: 1 tablet twice daily

Duration of treatment:

The treatment should be re-assessed if no improvement is seen after 14 days.

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

There is no specific information relating to overdosage. The recommended posology should be followed.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; cefalexin.

ATCvet code: QJ01DB01.

5.1 Pharmacodynamic properties

The product contains cefalexin, a first generation cephalosporin for oral administration. Cefalexin is a broad spectrum antibiotic with bactericidal activity against most gram-positive cocci, and some gram-negative bacteria (e.g. *E. coli*, *Proteus mirabilis*, *Klebsiella* and *Pasteurella multocida*). As for other beta-lactams the specific target sites of cephalosporins are the penicillin binding proteins (PBPs). Binding to PBPs causes an inhibiting effect on mucopeptid synthesis in the cell wall resulting in a bactericidal effect. The cephalosporins are usually penicillinase resistant.

5.2 Pharmacokinetic properties

The product is indicated for the treatment of canine pyoderma caused by *Staphylococcus intermedius*. Product specific pharmacokinetic data demonstrate that the proposed dosage of 25 mg/kg produces a clinically effective drug concentration in the skin. This level remains above the MIC (Minimum Inhibitory Concentration) of the etiologic agent of canine pyoderma (i.e. *Staphylococcus intermedius*) for 12 hours, indicating a sufficient dose interval.

Cefalexin is absorbed rapidly after oral administration. Peak plasma levels of Cefalexin are reached 1-2 hours after oral administration and C_{max} is about 30 microg/ml in plasma. Cefalexin is widely distributed through the organism (e.g. bone, muscle). Cefalexin is excreted renally in the active, non-metabolized form.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Lactose monohydrate
Microcrystalline cellulose
Talc
Magnesium stearate
Silica colloidal anhydrous

Film coating

Titanium dioxide (E171)
Talc
Polyethylene glycol 6000
Eudragit E 12.5
Magnesium stearate

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.
Protect from light.

6.5 Nature and composition of immediate packaging

Carton containing 20 blister strips, each containing 10 tablets.
Base layer foil of PVC/PVDC, push-through foil of aluminium.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10966/018/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

15th April 2010