

Part II
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFASEPTIN 120 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Active substance:

Cefalexin 120 mg
(as Cefalexin Monohydrate)

Excipient

Contains Titanium Dioxide (E171) as colouring agent 1.246 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

Dog

4.2 Indications for use, specifying the target species

Canine pyoderma caused by *Staphylococcus intermedius*.

4.3 Contra-indications

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

None

(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)

- 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 precautions have to be observed

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

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

Dogs of 5kg bw: 1 tablet twice daily
Dogs of 10kg bw: 2 tablets twice daily

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

Cephalosporins have a wide margin of safety and are unlikely to cause toxic signs even in overdose.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATC vet code: QJ01DA01

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*). Like 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.

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 aetiologic 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 µg/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

Other substances

Lactose Monohydrate
Microcrystalline Cellulose
Talc
Magnesium Stearate
Silica Colloidal Anhydrous

Film coating

Titanium Dioxide (E171)
Talc
Polyethylene Glycol 6000
Eudragit E12.5
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 15 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 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

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4098

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/7/99/12/7/04

10. DATE OF REVISION OF THE TEXT

January 2008