PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefaseptin 120mg film-coated tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each film coated tablet contains Cefalexin 120mg (as Cefalexin monohydrate 126.22mg) Titanium Dioxide E171

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

Carton contains 150 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Canine pyoderma caused by Staphylococcus intermedius

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Dogs of 5kg bw: 1 tablet twice daily

Dogs of 10kg bw: 2 tablets twice daily

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Not for use in animals with hypersensitivity to cefalexin or penicillin.

Can cause 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)

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]



To be supplied only on veterinary prescription

For Animal Treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

Buckingham Industrial Park

Buckingham

MK18 1PA

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4098

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

Vetoquinol UK Limited Vetoquinol House Great Slade Buckingham Industrial Park Buckingham MK18 1PA **Manufacturer and site of batch release:** Vetoquinol SA Lure, Cedex France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefaseptin 120mg film-coated tablets

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each film coated tablet contains:

Active Substance:

Cefalexin monohydrate 12.6.22 mg

(equivalent to Cefalexin 120 mg)

Excipient:

1.246mg Titanium Dioxide (E171) as colouring agent

4. INDICATION(S)

Canine pyoderma caused by Staphylococcus intermedius

5. CONTRAINDICATIONS

Animals with hypersensitivity to cephalexin or penicillin

6. ADVERSE REACTIONS

Can Cause:

- 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)

- Cefalexin monohydrate Ph. Eur.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

Dogs of 5kg bw: 1 tablet twice daily

Dogs of 10kg bw: 2 tablets twice daily

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not Applicable

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place. Protect from light. Keep out the reach of children.

12. SPECIAL WARNING(S)

For Animal Treatment Only

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, e.g. wearing impermeable gloves. Wash hands after administering the tablets.
- 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 with breathing, are more serious symptoms and require urgent medical attention.

4. Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of used packaging in household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2007

15. OTHER INFORMATION

POM-V To be supplied only on veterinary prescription *Vm* 08007/4098

Approved: 11/05/2018