PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefaseptin 600mg film-coated tablets for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each film coated tablet contains:

Active substance: Cefalexin (as Cefalexin monohydrate) 600mg

Excipient: 6.23mg Titanium Dioxide (E171) as colouring agent

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

Carton contains 200 tablets

5. TARGET SPECIES

Dog

6. INDICATION(S)

Canine pyoderma caused by *Staphylococcus intermedius*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Dogs of 12kg bw: ½ tablet twice daily

Dogs of 24kg bw: 1 tablet twice daily

For further information see package leaflet

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

User Information

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

Wash hands after use, see package leaflet for full user warnings and disposal advice.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep blister in outer carton

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

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

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

POM-V

To be supplied only on a 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 08007/4099

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

Site of batch release:
Vetoquinol SA
Lure, Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefaseptin 600mg film-coated tablets for dogs

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

Each film coated tablet contains:

Active substance:

Cefalexin (as Cefalexin monohydrate) 600mg

Excipient:

6.23mg Titanium Dioxide (E171) as colouring agent

4. INDICATION(S)

Canine pyoderma caused by *Staphylococcus intermedius*

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to cephalexin or penicillin

6. ADVERSE REACTIONS

- 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)

If you notice any serious or other effects not mentioned in this leadlet, please inform your veterinary surgeon.

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 12 kg bw: ½ tablet twice daily

Dogs of 24 kg bw: 1 tablet twice daily

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children

Do not store above 25°C

Protect from light

Store in a dry place

Do not use after the expiry date stated on the carton.

Keep blister in outer carton

To be supplied only on veterinary prescription

12. SPECIAL WARNING(S)

Where renal insufficiency exists, the dose rate should be reduced. Mild diarrhoea and vomiting can occur. However, where serious disturbances of the gastrointestinal tract occur, treatment should be discontinued.

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.

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

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

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.

User Warnings:

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 te face, lips or eyes or difficulty with breathing, as more serious symptoms and require urgent medical attention.
4. Wash hands after use

For Animal Treatment Only

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2009

15. OTHER INFORMATION

POM-V
Prescription only Medicine-Veterinarian
Vm 08007/4099

200 film coated tablets

Approved: 11/05/2018