PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephorum 250mg Film-coated Tablets for Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Cefalexin (as cefalexin monohydrate)

3. PHARMACEUTICAL FORM

Film coated tablets

4. PACKAGE SIZE

White polypropylene securitainers with white polyethylene snap on caps containing 50, 100 or 250 tablets.

PVC/PVDC – Aluminium foil blister packs containing 10 strips of 14 tablets each.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use. The recommended dose rate is 15 mg cefalexin / kg bodyweight twice daily. In severe or acute conditions the dose may be safely doubled to 30 mg/kg or given at more frequent intervals. Treatment for five days is recommended but this may be extended or shortened at the discretion of the veterinary surgeon.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in cases of known hypersensitivity to cefalexin. In cases of known renal insufficiency the dose should be reduced.
Read the package leaflet before use.
Operator safety: Cephalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin may lead to cross-sensitivity to cephalosporin and vice versa. Allergic reactions to these substances may occasionally serious. (1) Do not handle this product if you know you are sensitised, or if you have been advised not to be in contact 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.
Wash hands after use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Protect from light.
Keep the blisters in the outer carton.
Do not store above 25°C.

12. SPECIAL 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

For animal treatment only
To be supplied only on veterinary prescription

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

Keep out of the sight and of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

TVM UK Animal Health Ltd
Building B
Kirtlington Business Centre
Kirtlington
Oxfordshire
OX5 3JA

16. MARKETING AUTHORISATION NUMBER

Vm 46275/4002

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTER STRIP

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephorum 250mg Film-coated Tablets for Dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cefalexin (as cefalexin monohydrate)
Each tablet contains 250mg anhydrous cephalexin

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Keep the blisters in the outer carton

PACKAGE LEAFLET FOR:
Cephorum 250 mg film-coated tablets for dogs

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

Marketing authorisation holder
TVM UK Animal Health Ltd
Building B
Kirtlington Business Centre
Kirtlington
Oxfordshire
OX5 3JA

Manufacturer for the batch release
Sandoz GmbH
Biochemiestrasse 10, A-6250 Kundl
Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephorum 250mg film-coated tablets for dogs
Cefalexin (as cefalexin monohydrate)

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

Each tablet contains 250 mg cefalexin as 263 mg cefalexin monohydrate. Also contains 0.55 mg titanium dioxide (E171).

Cephorum 250 mg film-coated tablets are round, white to yellowish, biconvex tablets, scored on one side. ‘CX’ is imprinted above the scoreline, ‘250’ is imprinted below the scoreline. The tablets are not divisible.

4. INDICATION(S)

The product is indicated for the treatment of urinary tract infections in dogs caused by *Klebsiella pneumoniae* and for the treatment of bacterial skin infections in dogs, when susceptible organisms are present.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to cefalexin, to other cephalosporins, to other substances of the ß-lactam group or to any of the excipients. Do not use in rabbits, gerbils, guinea pigs and hamsters.

6. ADVERSE REACTIONS

Vomiting and/or diarrhoea have been observed in dogs. In rare cases hypersensitivity can occur. In cases of hypersensitivity reactions the treatment should be stopped.

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

7. TARGET SPECIES

Dogs

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

For oral use. The recommended dose rate is 15 mg cefalexin / kg bodyweight twice daily. In severe or acute conditions the above dose may be safely doubled to 30 mg/kg or given at more frequent intervals.
The table below is intended as a guide for the recommended dose of 15 mg cefalexin per kg bodyweight. Any increase in the dose should be calculated case-by-case for the individual animal concerned.

Bodyweight in kg	**Number of tablets per dose***
12 to 18	1 tablet
19 to 32	2 tablets
33 to 50	3 tablets

* Two doses per day should be given

Any increase in dose or duration of use (see below), and any use in dogs less than 12 kg bodyweight, should be in accordance with a risk/benefit assessment by the responsible veterinarian.

9. ADVICE ON CORRECT ADMINISTRATION

Treatment for five days is recommended but this may be extended or shortened at the discretion of the veterinary surgeon.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Protect from light. Keep the blisters in the outer carton. Do not store above 25°C.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

Special warnings for target species

None

Special warnings for use in animals

Special precautions for use in animals

Use of the product should be based on susceptibility testing and take in to account official and local antimicrobial policies.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefalexin and may decrease the effectiveness of treatment with other cephalosporins, or with penicillins, due to potential cross-resistance.

In case of an allergic reaction, treatment should be withdrawn.
As with other antibiotics which are excreted mainly by the kidneys, unnecessary accumulation may occur in the body when renal function is impaired. In cases of known renal insufficiency the dose should be reduced, antimicrobials known to be nephrotoxic should not be administered concurrently and the product should be used only according to a risk/benefit assessment by the responsible veterinarian.

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 reaction 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 be in contact 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 a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention. In case of accidental ingestion, seek medical attention immediately showing the physician this information.

Wash hands after use.

Use during pregnancy and lactation
The safety of the veterinary medicinal product has not been established in bitches during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
The bactericidal activity of cephalosporins is reduced by concomitant administration of bacteriostatic acting compounds (macrolides, sulphonamides and tetracyclines). Nephrotoxicity can be increased when 1st generation cephalosporins are combined with polypeptide antibiotics, aminoglycosides and some diuretics (furosemide). Concomitant use with such active substances should be avoided.

Overdose
Symptoms of overdose include nausea, vomiting, epigastric distress, diarrhoea and haematuria. Treatment should be symptomatic.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2020

15. OTHER INFORMATION

Product supplied either in white polypropylene securitainers with white polyethylene snap on cap containing 50,100 or 250 tablets or PVO PVDC - Aluminium foil blister packs containing 10 blister strips of 14 tablets each..

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

For animal treatment only

UK only: Vm 46275/4002 POM-V

IE only: VPE 10473/001/001 POM

Prescription only medicine

Approved 24 March 2020