# PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephorum 500 mg Film-coated Tablets for Dogs

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 500 mg Cefalexin (as 526 mg cefalexin monohydrate)

Also contains 1.1 mg titanium dioxide (E171)

## 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 reach and sight 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 46275/4000

## 17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

## MINIMUM PARTICULARS TO APPEAR ON BLISTER STRIP

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cephorum 500 mg Film-coated Tablets for Dogs

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cefalexin (as cefalexin monohydrate)
Each tablet contains 500 mg 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. To be supplied only on veterinary prescription.

Keep the blisters in the outer carton

# PACKAGE LEAFLET FOR:
Cephorum 500 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

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

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

Each tablet contains 500 mg cefalexin as 526 mg cefalexin monohydrate. Also contains 1.1 mg titanium dioxide (E171).

Cephorum 500 mg film-coated tablets are oblong, white to yellowish, biconvex tablets, scored on both sides.

## 4. INDICATION(S)

Indicated for oral antibiotic therapy in dogs. When susceptible organisms are present, Cephorum film-coated Tablets 500 mg are indicated for the treatment of bacterial skin infections and urinary tract infections caused by Klebsiella pneumoniae. Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

## 5. CONTRAINDICATIONS

Do not use in animals which are known to be hypersensitive to cefalexin. As with other antibiotics which are excreted mainly by the kidneys, accumulation may occur in the body when renal function is impaired. In cases of known renal insufficiency the dose should be reduced.

## 6. ADVERSE REACTIONS

Hypersensitivity to cefalexin is very rare. 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

The recommended dose rate is 15 mg/kg bodyweight twice daily. In severe or acute conditions the dose may be safely doubled or given at more frequent intervals. For oral administration.

## 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 reach and sight of children.
Protect from light. Keep container in the outer carton. Do not store above 25°C.
Shelf life of the veterinary medicinal product as packaged for sale (tubs and blister packs): 4 years. Do not use after the expiry date stated on the label.

## 12. SPECIAL WARNING(S)

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.

Although laboratory and clinical studies have shown no evidence of teratogenicity, caution should be exercised when prescribing for pregnant animals. Small quantities are found in the milk of nursing mothers.

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

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

Dispose of any 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

March 2020

## 15. OTHER INFORMATION

Product supplied either in white polypropylene tubs with white polyethylene snap on cap containing 100, 250 or 500 tablets or cartons of PVC/ PVDC/ Aluminium foil blister packs containing 10 strips of 14 tablets or 10 strips of 10 tablets.

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

For animal treatment only

UK only: Vm 46275/4005 POM-V

Approved 24 March 2020