

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Cephorum 500 mg film-coated tablets for dogs

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### Qualitative composition

#### Active ingredients:

Cefalexin monohydrate

#### Quantitative composition

Equivalent to 500 mg anhydrous cefalexin

#### Excipients:

Titanium dioxide (E171)

1.1 mg per tablet

For a full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Film coated tablet.

White to yellowish, elongated, film-coated tablet for oral administration, scored on both faces.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs

#### **4.2 Indications for use, specifying the target species**

Indicated for oral antibiotic therapy in dogs. When susceptible organisms are present, the product is indicated for the treatment of bacterial skin infections and urinary tract infections caused by *Klebsiella pneumoniae*.

#### **4.3 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.

#### **4.4 Special warnings for each target species**

None

#### **4.5 Special precautions for use**

##### **i. 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.

##### **ii. Special precautions for 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 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 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 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.

Wash hands after use.

#### **4.6 Adverse reactions (frequency and seriousness)**

Hypersensitivity to cefalexin is very rare.

#### **4.7 Use during pregnancy, lactation or lay**

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.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amount(s) to be administered and administration route**

For oral 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.

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.

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

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

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **Pharmacotherapeutic group:**

Antibacterial

#### **ATC Vet Code:**

QJ01DB01

#### **5.1 Pharmacodynamic properties**

Cefalexin is a broad spectrum cephalosporin antibiotic with bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria. The following have been shown to be sensitive to cefalexin *in vitro*: *Staphylococcus* spp (including penicillin-resistant strains), *Streptococcus* spp, *Corynebacterium* spp, *Pasteurella multocida*, *Escherichia coli* and *Klebsiella* spp.

#### **5.2 Pharmacokinetic properties**

Cefalexin is acid stable, well absorbed following oral administration either with or without food, and is excreted by renal tubular secretion and glomerular filtration. The elimination half life in the dog is approximately 90 minutes.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Titanium dioxide (E 171)  
Povidone K25  
Sodium starch glycollate (Type A)  
Magnesium stearate  
Macrogol 6000  
Lactose monohydrate  
Hypromellose (methocel E 15)  
Talc  
Peppermint oil  
Saccharin sodium

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale in tubs: 4 years

Shelf life of the veterinary medicinal product as packaged for sale in blister packs:  
4 years

### **6.4 Special precautions for storage**

Protect from light.  
Do not store above 25°C.

### **6.5 Nature and composition of immediate packaging**

White polypropylene securitainer with white polyethylene snap on caps containing 100, 250 or 500 tablets.

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

Not all pack sizes may be marketed.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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**

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

**8. MARKETING AUTHORISATION NUMBER**

Vm 46275/4000

**9. DATE OF FIRST AUTHORISATION**

11 May 2005

**10. DATE OF REVISION OF THE TEXT**

March 2020

A handwritten signature in black ink, consisting of several vertical strokes followed by a long, sweeping horizontal stroke that curves upwards at the end.

Approved 24 March 2020