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	Quantitative composition
Active ingredients:	
Cefalexin monohydrate	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. Hypersenitivity 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 excised 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

Approved 24 March 2020