Only for Veterinary Use

Cephaset® %15

Suspension for Injection

Veterinary Systemic Antibacterial

COMPOSITION

It is a cream – white colored sterile suspension for injection which contains cephalexin monohydrate equivalent to 150 mg cephalexin per ml.

PHARMACOLOGICAL PROPERTIES

CEPHASET 15% contains cephalexin which is a first generation cephalosporin. Main core of cephalosporin is comprised of 7-aminocephalosporanic acid (7-ASA), which is cephem derivative. Cephalexin exerts bactericide effect by inhibiting last stage of peptidoglycan exchange synthesis (transpeptidase reaction) in cell wall of the bacteria and activating autolytic enzymes. Cephalexin exerts effects against both Gram positive and Gram negative bacteria, but it is effective particularly against Gram positive bacteria.

Principal bacteria susceptible to cephalexin include E.coli, Proteus sp., Klebsiella sp., penicillinase positive Staphylococcus sp. and penicillin-resistant Staphylococcus aureus. Anaerobic bacteria, indol-positive Proteus species, Bac. fragilis, Enterobacter, Serratia, Citrobacter, Acinetobacter and Pseudomonas are resistant.

Cephalexin is distributed to whole body following intramuscular administration. Peak plasma concentration is 5.6 ± 0.79 µg/ml when it is intramuscularly administered to cattle. When it is at dose of 7.5 mg/kg, serum concentration remains above for 11-14 hours if it is subcutaneously administered or for 8-9 hours if it is intramuscularly administered. It is excreted into pleural fluid, synovial fluid, pericardial fluid and urine at therapeutic concentrations. It is poorly found in CSF. Excretion is largely via glomerular filtration in kidneys.

AREA OF USE/INDICATIONS

CEPHASET 15% is used for treatment of infections caused by bacteria susceptible to cephalexin in cattle, cats and dogs:

For treatment of infections caused by Staph.aureus, E.coli, Proteus miribalis and Klebsiella sp.;

For treatment of respiratory system and urinary system infections caused by susceptible bacteria;

For treatment of acute mastitis, septicemia, skin and soft tissue infections, foot diseases and bone and joint diseases.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Unless otherwise advised by veterinary surgeon, pharmacological dose of the preparation is 7.5-10 mg/kg live body weight for cattle and 10 mg/kg live body weight for cats and dogs. Practical dose is as follows:

Kid – calf, cattle: 1 ml for 15-20 kg live body weight is intramuscularly administered in 24-hour intervals for 3-5 days ;

Cat – Dog: 1 ml for 15 kg live body weight is intramuscularly administered in 24-hour intervals for 3-5 days. Shake the preparation before use.

ADVERSE / SIDE EFFECTS

There is almost no adverse effect if recommended doses are observed. Nausea, vomiting, diarrhea and allergic reactions may occur in animals hypersensitive to cephalexin. In addition, fever can be seen in cats and irritation may occur in dogs, although they are rare.

DRUG INTERACTIONS

If it is concomitantly used with nephrotoxic products such as aminoglycosides and amphotericin B, all cephalosporin compounds may lead to nephrotoxic effect. It should not be concomitantly used with tetracyclines, phenicoles and macrolides.

SYMPTOMS, PRECAUTIONS AND ANTIDOTE IN OVERDOSE

Although rare, diarrhea and ache may occur in cats, while loss of appetite may occur in dogs. In such event, treatment with this drug should be discontinued.

WARNINGS FOR THE DRUG RESIDUES IN NUTRIENTS

Withholding Period (WHP): Cattle should not be transferred to slaughtering throughout the treatment or within 4 days following the last administration of the drug. Legal Withholding Period is "0" day for milk.

CONTRAINDICATIONS

It should not be used in animals sensitive to penicillin and derivatives. It should not be used in animals with serious renal disorder.

GENERAL WARNINGS

Please refer to the veterinary surgeon before use and in case of an unexpected effect. **Keep out of the reach of children.**

PRECAUTIONS TO BE TAKEN BY ADMINISTRATOR AND WARNING FOR VETERINARY SURGEON:

Contact of penicilin and cephalosporing with allergic subjects via injection, inhalation, digestion and direct contact may lead to allergic reactions (hypersensitization). Allergic reactions to those substances may sometimes lead to serious health problem. Therefore,

- These groups of drugs should not be administered to subjects with known allergy to penicillin and cephalosporin.
- Necessary precautions should be taken in order not to contact with the drug during administration.
- If allergic symptoms such as pustules occur due to contact with the drug, a doctor should be contacted. Facial, ocular and lip swelling and breath shortness are more serious symptoms which require emergency intervention.
- If ocular contact accidentally occurs, eyes should be irrigated with water for 15 minutes.

WARNING FOR NON-TARGETED SPECIES

It should not be used in rabbits and hamsters. Moreover, it should not be used in snakes and totipalmate poultry (ie, duck and goose).

Administration to horses may lead to gastrointestinal disorders including colitis.

STORAGE CONDITIONS AND SHELF LIFE

It should be stored at 25° C away from direct exposure to light and it should not be frozen. It should be used within 28 minutes after bottle is opened. Shelf life is 2 years from the date of production.

COMMERCIAL SUPPLY INDICATING COMPOSITION AND QUANTITY OF PACKAGING

CEPHASET Suspension for Injection is supplied in 20, 50, 100 ml and 250 ml colorless glass vials in cardboard boxes.

SALE PLACE AND CONDITIONS

It is sold in the veterinary clinics and the pharmacies with prescription written by veterinary surgeon (VP).

PROSPECTUS APPROVAL DATE: 09.10.2009

DATE AND NUMBER OF LICENSE AWARDED BY THE MINISTRY OF AGRICULTURE AND RURAL AFFAIRS: 06.10.2009-21/089

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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