For Veterinary Use Only.

Enrolen®

10% Solution for Injection

Veterinary Systemic Antibacterial

COMPOSITION:

Enrolen 10% Solution for Injection is a clear, yellowish, odourless, viscous solution containing 100mg enrofloxacine per each ml.

PHARMACOLOGICAL PROPERTIES:

Enrofloxacine from fluoroquinolone group is a broad spectrum antibacterial including gram-positive and gram-negative bacteria and mycoplasmas. Enrofloxacine, which is effective even at low concentrations, has characteristics such as a good diffusion profile, high bioavailability and long serum half life. Enrofloxacine inhibits the function of DNA gyrase enzyme in bacteria and blocks DNA replication.

The major sensitive bacteria are E.coli, Salmonella sp., Enterobacter sp., Serratia sp., Proteus sp., Klebsiella sp., Shigella sp., Yersinia sp., Moraxella sp., Acinobacter sp., Actinobacillus sp., Pasteurella sp., Leptospira sp., Campylobacter sp., Citrobacter sp., Haemophilus sp., Ehrlichia sp., Coxiella brunetti; Staphylococcus sp. including the ones sensitive to methicilline and gentamicine; N.gonorrhoeae, N. meningitidis, Corynebacterium sp., Chlamydia sp., V.cholerae, Mycoplasma sp. including the ones sensitive to penicilin.

Strep, suis, Strep, agalactia, Strep dysgalactia, Strep, zooepidemicus, R.equi, Mycobacterium sp. are moderately sensitive. Most of the anaerobic coccus, Clostridium sp., Bacteroides sp., and Ps. Maltophila are generally less sensitive or resistant to quinolones. The absorption of Enrolen 10% Solution for Injection administered parenterally is followed by a rapid diffusion and slow elimination phase. It reaches the maximum plasma level within an hour following its administration. Its concentrations in the tissues reach a few times of the level in serum and it maintains its effective level for 12-24 hours. The ratio of binding to proteins is 36-45% in cattle and 22% in horses. When administered intravenously its elimination half life (t 1/2β) is 2.7 hours in cattle and 3.87 hours in sheep. Maximum blood concentration (Cmax) is 1.94 µg/ml in sheep and 2.8 µg/ml in cattle.

AREA OF USE / INDICATIONS:

It is used in cattle and sheep for the treatment of infections caused by gram-negative and gram-positive bacteria which are sensitive to enrofloxacine and by Mycoplasmas. In this sense, it is administered as parenteral treatment supportive of local application in respiratory system infections such as pneumonia, pleuropneumonia and enzootic pneumonia caused by Pasteurella haemolytica and Pasteurella multocida; E. Coli infections (Colibacillosis, Coliseptisemi) in lamp and yeans; infections of digestive and urogenital system; secondary infections accompanied by viral infections developed by sensitive bacteria; mastitis and metritis.

USAGE AND DOSAGE:

Enrolen 10% Solution for Injection is administered parenterally through subcutaneous (SC), intramuscular (IM) and intravenous (IV) routes. Daily general dose of enrofloxacine is 2.5mg/kg live weight. Unless otherwise recommended by the veterinary surgeon the general treatment period is 3 days. This dose may be doubled and the administration period may be quintupled in complicated infections of respiratory tract and Salmonellosis.

Enrolen 10% Solution for Injection is administered at a dose of 1ml/40kg live weight. While using asepsis and antisepsis should be followed.

UNDESIRED/SIDE EFFECTS

It may lead to articular cartilage disorders especially in young animals in rapid growth period. Quinolones rarely cause convulsions. Therefore, it should be administered with special care in animals with known or suspected disorders regarding central nervous system. Certain quinolones such as ciprofloxacin and enrofloxacine may lead to crystallization in urinary tract. Therefore, water restriction should be avoided during the administration of these drugs.

DRUG INTERACTIONS:

The administration of enrofloxacine together with other drugs known to be metabolized in the liver may affect the pharmacokinetics of the relative drugs. Quinolones extend the half life of theophylline, coumarin derivatives, methyl xanthines and non-steroid analgesics. There are synergistic interactions between fluoroquinolones and aminoglycosides, and beta-lactam drugs and sulphonamides; whereas antagonist interactions between phenycols, erythromycin, polymyxin, nitrofurantoin and rifampin.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP): The meat type cattle and sheep should not be sent for slaughter before 14 and 10 days, respectively, following the final drug administration and during the treatment. The cow milk produced should not be offered for human consumption during the treatment and for 4 days (8 milkings) following the final administration. It should not be administered to sheep from which milk is produced for human consumption.

CONTRAINDICATIONS:

It is contraindicated in animals with liver and kidney failure. It should not be used in horses and young breeding animals.

Use during pregnancy: Avoid administering quinolones in pregnant animals due to its undesired effects over cartilage tissue in young animals.

GENERAL WARNINGS:

Consult your veterinary surgeon before using and in case an unexpected effect is observed. Keep out of reach of children.

PRECAUTIONS TO BE TAKEN BY THE USER

In case of skin and eye contact, wash with plenty of water. Wash your hands following drug administration. People with sensitivity to quinolones should avoid contact with the drug. In case of exposure to excessive amount of the drug avoid sun light.

STORAGE CONDITIONS AND SHELF LIFE:

Store at room temperature (15-25℃).

Protect from light. Shelf life is 3 years as of the production date.

Opened vials should be used within 28 days.

WARNINGS FOR NON-TARGET SPECIES:

Due to its side effect over the cartilage tissue, it should be taken into consideration that it should not be administered to cats, small dogs, middle dogs and big dogs before 2, 8, 12 and 18 months, respectively; and that it may rarely cause visual defects in cats at quadruplicate (20 mg/kg) doses and more.

COMMERCIAL PRESENTATION FORM:

Presented to the market in 20, 50 and 100ml brown vials in cardboard boxes.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries (VPS).

APPROVAL DATE OF PACKAGE INSERT: 21.09.2004

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS

MARKETING AUTHORIZATION DATE AND NO: 02.04.1997 - 8/805

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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