For Veterinary Use Only.

GentaPan®

15% Solution for Injection

Veterinary Systemic Antibacterial

COMPOSITION:

A colorless and clear solution containing gentamicin sulphate equivalent to 150 mg gentamicin base per each ml.

PHARMACOLOGICAL PROPERTIES:

GentaPan 15% Solution for Injection containing gentamicin which is among the aminoglycoside antibiotics group is a broad spectrum antibiotic solution intended to be used for cattle and horses. Gentamicin passes through bacteria cell membrane via active transport. It affects bacteria by means of affecting 30 S ribosomal subunits and inhibiting their coupling with mRNA and causing codon misreading on RNA. As a result, protein synthesis is inhibited and the cell loses its vitality. The main sensitive bacteria to gentamicin are Enterobacter spp., E. coli, Klebsiella spp., Serratia spp., Yersinia spp., Campylobacter spp., Haemophilus spp., Pasteurella spp. most of the Pseudomonas aeruginosa strains and Staph. Aureus. However, other gram-positive bacteria including Streptococcus spp., certain Pseudomonas spp. and anaerobe bacteria are resistant. When administered intramuscularly it is quickly absorbed and reaches the effective concentration within 15 minutes and the peak plasma concentration in 30-60 minutes. It is mainly diffused into kidney, liver and muscles. Gentamicin is mainly excreted from the body through urine by glomerular filtration, without being changed. Its biological half life in blood serum is approximately 75-110 minutes. When administered at normal treatment doses, its effective concentration reached at the plasma is between 4 and 8µg/ml. Gentamicin which gets into circulation never bind to plasma protein. It binds to red blood cells ca. 10%.

AREA OF USE / INDICATIONS:

GentaPan 15% Solution for Injection is administered to cattle and horses for the infections of respiratory, digestive and urogenital system (nephritis, pyelonephritis and cystitis) caused by sensitive bacteria, colibacillosis, septicaemia and other soft tissue infections.

USAGE AND DOSAGE:

GentaPan 15% Solution for Injection is administered intravenously (IV), intramuscularly (IM) and subcutaneously (SC) to cattle and horses. Unless otherwise recommended by the veterinary surgeon the daily dose of gentamicin per each live weight in horses and cattle is 3.5-4mg/kg. The dose is divided into two parts on the first day and the treatment continues for 2-3 days once in a day.

Calf-Foal	: 1ml / 40kg live weight/day
Calf	: 2 ml / 80 kg live weight/day
Cattle-Horse	: 5 ml / 200 kg live weight/day

Avoid overdose and pay attention to dose adjustment for the animals, especially which are underweight and small in size. Also, aminoglycosides are not transmitted to adipose tissue ever so. Therefore, the live weight of normal animals should be taken into consideration while adjusting the dose for fatty animals.

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES:

The toxicity of aminoglycosides increases in hypovolemic animals. Therefore, this factor is taken into consideration for the treatment of these animals and it is recommended to ensure the rehydration of the patient. It is recommended to keep in mind that during the treatment of gram negative bacterial infections with aminoglycosides, endotoxin level in the blood increases and causes shock, and to take precautions accordingly. All aminoglycosides decrease blood pressure and cardiac output and slow down blood rate. Also they decrease blood total calcium level. The age of the animal, shock, acidosis, acute renal failure, hepatic dysfunction, sepsis, previous exposure to aminoglycosides, electrolyte imbalance and hypotension may increase sensitivity to aminoglycosides. Due to its potential interactions with other drugs, read the part regarding drug incompatibility.

UNDESIRED/SIDE EFFECTS

Hypersensitivity reaction may be observed, albeit rare, in animals which are sensitive to aminoglycosides. Due to its autotoxic and nephrotoxic effects, irreversible disorders may be developed in organelles of hearing and balance, and kidneys. This depends on the duration and dosage of the treatment. Therefore, recommended dose should be observed. Aminoglycosides have serious undesired effects over kidney and organ of hearing. Also, they cause neuromuscular blockage. Temporary reaction may be seen in the injection area of dogs.

DRUG INTERACTIONS:

Due to its side effects, aminoglycosides should not be administered concurrently with other aminoglycosides and neurotoxic, nephrotoxic and autotoxic treatments. Also, they should not be used in combination with drugs which have harmful effects over kidneys such as tetracyclines and sulphonamides, with other drugs creating neuromuscular blockage, and with analgesics and nonsteroidal anti-inflammatory drugs. In case of administration with iron preparations, furosemide, amphotericin B, polymyxin B, vancomycin and cephalotin, the toxic effect over kidneys and internal ear will be increased. Gentamicin should not be used with ampicilin sodium, furacemide, cephalotin sodium, heparin sodium and cephapirin sodium.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP): The meat type cattle should not be sent for slaughter before 80 days following the final drug administration and during the treatment. Milk produced should not be offered for human consumption during the treatment and 2 days (4 milkings) following the final administration.

CONTRAINDICATIONS:

Avoid administering to animals with known sensitivity to aminoglycosides, especially kidney and/or liver failure, and diseases regarding organs of balance and hearing.

Use during pregnancy: Pay attention as it may lead to foetal autotoxicity.

GENERAL WARNINGS:

Consult your Veterinary Surgeon before using and in case an undesired effect is observed. Keep out of reach of children.

OVERDOSE AND PRECAUTIONS TO BE TAKEN:

Avoid overdose during treatment with aminoglycosides. In cases of overdose, edrofonium (0,5mg/kg), calcium chloride (10-20mg/kg), calcium gluconate (30-60mg/kg) or neostigmine (100-200mcg/kg) may be used in order to inhibit neuromuscular blockage. So as to inhibit renal toxicity, aminoglycoside administration should be discontinued and polyionic liquid treatment should be started in order to ensure diuresis.

STORAGE CONDITIONS AND SHELF LIFE:

Store at room temperature of (15-25℃) protected from light. Shelf life is 3 years as of the production date. Opened vials should be used within 30 days.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE:

Offered for sale in 20, 50, 100ml amber vials in cardboard box packages and in 250ml amber vials in plastic boxes.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 22.03.2005

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE AND NO: 08.03.2005-14 / 045

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk. No: 18, 34896 Pendik-ISTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat

CAK031