Leaflet

For Veterinary Use Only
GENTAVILIN 10%
Solution For Injection
Veterinary Systemic Antibacterial

COMPOSITION

Gentavilin 10% is a colorless or slightly yellow solution containing gentamicin sulfate equivalent to 100 mg gentamicin per ml.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Gentamicin sulfate directly acts on bacterial ribosomes, inhibiting protein synthesis and reducing the suitability of genetic code translation. The substance is highly polar, and its transport appears to be an active process closely linked to electron transport across the cell membrane, oxidative phosphorylation, and respiratory quinones. The antimicrobial activity is primarily directed against aerobic Gram-negative bacteria.

Its main activity is against Gram-negative bacteria. The breakpoints for gentamicin are 4 µg/ml for sensitive (S) and 16 µg/ml for resistant (R) strains (Source: CLSI 2008).

Resistance to aminoglycosides is primarily produced by enzymes encoded by genes located on bacterial plasmids. These enzymes act within the bacteria to modify aminoglycosides, thus preventing their binding to ribosomes. This type of plasmid-mediated resistance can be transferred between bacteria. A single type of plasmid can offer cross-resistance to multiple aminoglycosides and other unrelated antimicrobials.

Pharmacologial Properties

Gentamicin sulfate is poorly absorbed from the gastrointestinal system, therefore the product must be administered parenterally for systemic effect. Gentamicin is rapidly absorbed after intramuscular injections, reaching peak plasma concentrations within ½ to 2 hours. It appears in synovial and peritoneal fluids, but effective levels are not achieved in cerebrospinal fluid, bronchial secretions, ocular fluids, or milk. Elimination occurs primarily through glomerular filtration and is rapidly excreted in the urine.

Gentamicin is a highly polar drug with poor tissue penetration; it primarily distributes into extracellular fluids.

AREA OF USE/INDICATIONS

Used for the treatment of infections caused by gentamicin-sensitive bacteria in cattle, dogs, and horses:

Cattle:

- Gastrointestinal system infections
- Urogenital system infections
- Septicemia

Dogs and Cats:

- Respiratory tract infections
- Gastrointestinal system infections
- Urogenital system infections
- Ear infections (acute and chronic bacterial outer ear infections)
- Septicemia

Horses:

Used for the treatment of lower respiratory tract infections caused by gentamicin-sensitive Gram-negative aerobic bacteria.

USAGE AND DOSAGE

To ensure the correct dosage, the body weight must be determined as accurately as possible.

Cattle: Administered intramuscularly or intravenously.

The dosage is 2 mg of gentamicin/kg body weight (2 ml of the product for every 100 kg of body weight) twice a day for 3-7 days. If the dose volume is large, it should be divided into smaller doses.

Horses: Administered intravenously once a day at a dose of 6.6 mg/kg body weight (approximately 6.5 ml of the product for every 100 kg of body weight) for 3-5 days.

The use in newborn foals is not recommended.

Dogs and Cats: Administered intramuscularly or subcutaneously, starting with 4 mg/kg on the first day, given twice a day (0.2 ml of the product for every 5 kg of body weight), and then once a day for 3-5 days.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

Repeated injections may cause reactions at the injection site.

Aminoglycosides, such as gentamicin, may increase endotoxin levels in the blood during the treatment of Gram-negative bacterial infections, which can potentially lead to shock. Precautions should be taken in these cases.

All aminoglycosides decrease blood pressure, cardiac output, and heart rate, and also lower total calcium levels in the blood.

Factors that increase sensitivity to aminoglycosides include the animal's age, shock, acidosis, acute renal failure, hepatic dysfunction, sepsis, prior exposure to aminoglycosides, electrolyte imbalance, and hypotension.

Dehydrated animals should have their fluid balance corrected from the beginning of treatment.

Gentamicin injections should be given slowly to prevent neuromuscular blockage.

Gentamicin is a narrow-spectrum bactericidal antibiotic and is ineffective against anaerobic bacteria and mycoplasmas.

Gentamicin does not penetrate cells or abscesses and is inactivated in inflamed tissue, low pH, and low oxygen conditions.

The dosage regime should not be exceeded.
The product should be used based on sensitivity test results whenever possible.
Deviating from the recommended usage can increase the risk of nephrotoxicity and increase the prevalence of gentamicin-resistant bacteria.
Caution should be exercised when using this product with NSAIDs, furosemide, and other nephrotoxic drugs.
Even at therapeutic doses, gentamicin is known to cause nephrotoxicity. Ototoxicity has also been reported.
Gentamicin has a narrow therapeutic window, and it should only be used under veterinary supervision, considering alternative treatments and performing a benefit-risk assessment.
To reduce the risk of nephrotoxicity, ensure the animal is adequately hydrated during treatment, and if necessary, provide fluid therapy.
Close monitoring of horses treated with gentamicin is strongly recommended, including checking kidney function (e.g., creatinine, urea) and urine analysis (e.g., gamma-glutamyl transferase/creatinine ratio).
Therapeutic levels of gentamicin in the blood should be monitored. When blood monitoring is possible, the plasma peak concentration should be between 16–20 μg/ml.
Gentamicin has not been studied for safety in foals, especially newborn foals, and its use in foals is not recommended due to a higher risk of nephrotoxicity compared to adults.
Young animals metabolize gentamicin more slowly than adults.
Special care should be taken when using gentamicin in elderly, endotoxemic, septic, or dehydrated horses.
The product's tolerance in newborn foals has not been assessed.
Use in Pregnancy, Lactation, and Egg-Laying: Do not use in pregnant cattle.
The safety of gentamicin in pregnant horses is unknown. However, studies in laboratory animals show that gentamicin can cause fetal nephrotoxicity. It should only be used if the veterinarian deems the benefit-risk ratio appropriate.
This summary emphasizes the importance of correct dosing, the potential risks (especially nephrotoxicity and ototoxicity), the need for careful monitoring, and specific precautions during pregnancy, lactation, and foal use.

ADVERSE EFFECTS
Especially cats are sensitive to gentamicin. Local reactions may occur at the injection site, particularly with repeated injections in the adjacent area. Mild, persistent reactions may develop at the injection site. In cats, especially at high doses or with repeated treatments, the product can cause severe nephritis and damage to the balance and hearing organs. If ataxia and vomiting occur, the treatment should be discontinued.

DRUG INTERACTIONS

Other aminoglycoside antibiotics or other drugs known to induce ototoxicity or nephrotoxicity (such as tetracyclines, sulfonamides, etc.), general anesthetics, muscle relaxants, and polymyxins should not be used together. Non-steroidal anti-inflammatory drugs, other neuromuscular blocking agents, iron preparations, furosemide, and other diuretics should not be used together. Halothanes increase the cardiovascular depression effect of gentamicin.

It should not be used in combination with other veterinary medicinal products. This product is incompatible with alkaline products. Gentamicin should not be used in the same syringe as cephalosporins, chloramphenicol, or sulfonamides.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

The product has not been specifically tested in overdose studies, and therefore, no safety margin has been established.

Overdose should be avoided during treatment with aminoglycosides. In case of overdose, one of the following options can be used for neuromuscular blockade: edrophonium (0.5 mg/kg), calcium chloride (10 - 20 mg/kg), calcium gluconate (30 - 60 mg/kg), or neostigmine (100 - 200 mcg/kg).

For renal toxicity, aminoglycoside administration should be stopped, and polyionic fluid therapy should be administered to promote diuresis.

WITHDRAWAL PERIODS

Due to the accumulation of gentamicin in the liver, kidneys, and injection site, repeated administrations should be avoided during the residue clearance period.

Meat: 139 days (103 days for calves) if treated for 3 days, 192 days if treated for 6 days, and 214 days if treated for 7 days.

Milk: 7 days (14 milkings).

CONTRAINDICATIONS

Do not use in cases of kidney disorders, dehydration, hearing problems, balance issues, and middle ear infections. Do not use in combination with strong diuretics or potentially nephrotoxic medications. Should not be used in exotic animals as it may lead to kidney failure. If used with muscle relaxants, it should not be administered intravenously or through abdominal injection. Do not use in animals known to be sensitive to gentamicin and other aminoglycoside antibiotics. Do not apply concurrently with bacteriostatic antibiotics. Do not apply in animals resistant to gentamicin, kanamycin, streptomycin, dihydrostreptomycin, and paromomycin. Do not use in animals weighing less than two kilograms.

GENERAL WARNINGS

Consult a veterinarian before use and if any unexpected effects occur. Keep out of reach of children.

PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR AND WARNINGS FOR VETERINARY SURGEON

Individuals known to be sensitive to gentamicin should avoid contact with the veterinary medicinal product. The veterinary medicinal product should be applied carefully. In case of accidental injection, seek medical help immediately and show the packaging label and leaflet to the doctor.

STORAGE CONDITIONS AND SHELF LIFE

Before and after opening it should be stored in the original packages, protected from light, and stored below 25°C without placed in the refrigerator or freezer. The shelf life is 3 years.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES

Used or leftover products should be disposed of according to the relevant regulations.

COMMERCIAL PRESENTATION FORM

50 ml, 100 ml and 250 ml amber-colored Type II glass vials with stoppers and flip-off in boxes.

APPROVAL DATE OF LEAFET: 29.08.2023

MARKETING AUTHORIZATION DATE AND NO: 07.05.2001 – 10/944

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER

VİLSAN Veteriner İlaçları Tic. Ve San. A.Ş.
Balıkhisar Mah. Balıkhisar Köy İçi Küme Evleri No: 765A Akyurt/Ankara – Türkiye

MANUFACTURER COMPANY

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Balıkhisar Mah. Balıkhisar Köy İçi Küme Evleri No: 765A Akyurt/Ankara – Türkiye

Made in Turkiye

Label

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Horses: Administer 6.5 ml of the product per 100 kg body weight via intravenous injection.

Dogs and Cats: Administer 0.2 ml of the product per 5 kg body weight via intramuscular or subcutaneous injection.

For detailed information, please read the package leaflet.

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Box

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