Leaflet

For Veterinary Use Only
GENTAVILIN
Solution For Injection
Veterinary Systemic Antibacterial

COMPOSITION

It is a colorless, clear solution that containing Gentamicin sulfate equivalent to 50 mg Gentamicin per ml.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Gentamicin sulfate directly affects the bacterial ribosome by inhibiting protein synthesis and reducing the appropriateness of genetic code translation. The substance is highly polar, and transport is closely linked to electron transport within the cell membrane, oxidative phosphorylation, and respiratory quinones, which appear to be active processes. Antibacterial activity is primarily directed against aerobic gram-negative bacteria.

The breakpoints for Gentamicin are 4 µg/ml for susceptible (S) and 16 µg/ml for resistant (R) (Source: CLSI 2008).

Resistance to aminoglycosides is primarily produced by enzymes encoded by genes located on bacterial plasmids. These enzymes act inside the bacterium to modify aminoglycosides, thus preventing them from binding to ribosomes. This type of plasmid-associated resistance can be transferred between bacteria. A single type of plasmid may confer cross-resistance to multiple aminoglycosides and resistance to other unrelated antimicrobials.

Pharmacokinetics Properties

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

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

AREA OF USE/INDICATIONS

It is used in the treatment of infections caused by gentamicin-sensitive bacteria in cattle, horses, dogs, and cats, as reported below:

Cattle:

- Gastrointestinal system infections
- Urogenital system infections
- Septicemias

Dogs, Cats:

- Respiratory tract infections
- Gastrointestinal system infections
- Urogenital system infections
- Ear infections (acute and chronic bacterial external ear infections)
- Septicemias

Horses:

- Treatment of 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.

In cattle, it is administered intramuscularly or intravenously. Subcutaneous administration is not recommended.

It can be given twice a day at a dosage of 2 mg gentamicin/kg body weight (4 ml of the product for every 100 kg body weight) for 3-7 days. If the dose volume is large, it should be divided and administered in multiple doses.

In horses, it can be administered intravenously once a day at a dosage of 6.6 mg/kg body weight (approximately 13 ml of the product for every 100 kg body weight) for 3-5 days.

It is not recommended for use in newborn foals.

In dogs and cats, it is administered intramuscularly or subcutaneously, initially twice a day at a dosage of 4 mg/kg (0.4 ml of the product for every 5 kg body weight) 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.

It is recommended to remember that during the treatment of gram-negative bacterial infections with aminoglycosides, the level of endotoxins in the blood may increase, potentially leading to shock, and appropriate precautions should be taken. All aminoglycosides lower blood pressure and cardiac output, and slow down heart rate. They also decrease total blood calcium levels. Factors such as the animal's age, shock, acidosis, acute renal failure, hepatic dysfunction, sepsis, prior exposure to aminoglycosides, electrolyte imbalance, and hypotension increase sensitivity to aminoglycosides.

In dehydrated animals, fluid balance should be corrected from the start of treatment.

Due to the possibility of neuromuscular blockade during gentamicin injection, the injection should be performed very slowly.

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

Gentamicin does not penetrate cells or abscesses. It is inactivated in inflamed tissue debris, low pH, and hypoxic environments.

The dosage regimen should not be exceeded.
This product should be used according to sensitivity test results whenever possible.
Using this product in a manner other than what is specified in the product characteristics can increase the risk of nephrotoxicity and the prevalence of gentamicin-sensitive bacteria.
Extreme caution should be exercised when using this product with other potentially nephrotoxic products such as NSAIDs, furosemide, and other aminoglycosides.
Horses:
It is known that gentamicin can cause nephrotoxicity even at therapeutic doses. Ototoxicity caused by gentamicin has also been reported. The safety margin of gentamicin is narrow. This product should only be used by a veterinarian, considering alternative treatments and a benefit-risk assessment.
To reduce the risk of nephrotoxicity, it should be ensured that the treated animals are adequately hydrated, and fluid therapy should be given if necessary.
Close monitoring of horses receiving gentamicin is strongly recommended. With this monitoring, blood parameters related to kidney function (such as creatinine, urea) and urine (such as gamma-glutamyl transferase/creatinine ratio) should be analyzed. Due to individual fluctuations in plasma peak and trough levels, it is recommended to monitor the therapeutic levels of gentamicin in the blood. When blood monitoring is possible, the plasma peak concentration should be between 16-20 μg/ml.
The safety of gentamicin in foals has not been studied, and therefore, there is no information about its effects in foals, especially newborns. According to available information, gentamicin carries a higher risk of nephrotoxicity in foals, particularly in newborns, compared to adults.
Gentamicin has a slower clearance in young animals compared to adults. For these reasons, the use of gentamicin in foals is not recommended.
Special caution should be observed when using it in older, endotoxemic, septic, and dehydrated horses.
The tolerance of the product in newborn foals has not been evaluated.
Use during pregnancy: Do not use in pregnant cattle. The safety of this product in pregnant horses is unknown. However, studies conducted in laboratory animals have shown that gentamicin has fetal nephrotoxicity. It may only be used based on the veterinarian's benefit-risk assessment.

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

DRUG INTERACTIONS

Other aminoglycoside antibiotics or 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 drugs that cause neuromuscular blockade, iron preparations, furosemide, and other diuretics should not be used together. Halothane increases the cardiovascular depression effect of gentamicin.

It should not be used 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 may 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, the administration of aminoglycosides 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) after 3 days of intramuscular or intravenous administration at the recommended dose, 192 days after 6 days of administration, and 214 days after 7 days of administration.

Milk: 7 days (14 milkings).

CONTRAINDICATIONS

Do not use in cases of kidney disorders, dehydration, hearing problems, balance issues, or middle ear infections.

Should not be used in combination with potent diuretics and other potentially nephrotoxic medical drugs.

Its use in exotic animals is not recommended, as it may lead to kidney failure.

If used with muscle relaxants, it should not be administered intravenously or as an abdominal injection.

Do not use in animals known to be sensitive to gentamicin or other aminoglycoside antibiotics.

Do not administer simultaneously with bacteriostatic antibiotics.

Do not use in animals that show resistance 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 are observed. Keep out of reach of children and away from foodstuffs.

PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR AND WARNINGS FOR VETERINARY SURGEON
People 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 product packaging, unused or remaining product should be disposed of in accordance with the relevant regulations.

COMMERCIAL PRESENTATION FORM
50 ml and 100 ml amber-colored Type II glass vials with stoppers and flip-off in boxes.

PLACE AND CONDITIONS OF SALE
It is sold in pharmacies and veterinary clinics with a veterinarian's prescription. (VSP)

APPROVAL DATE OF LEAFET: 11.02.2025

MARKETING AUTHORIZATION DATE AND NO: 11.11.1997 – 009/0803

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

Made in Turkiye

Label

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Cattle: It is administered intramuscularly or intravenously. Subcutaneous administration is not recommended. The product can be administered twice a day at a dosage of 4 ml per 100 kg of body weight for 3-7 days.
Horses: It is administered intravenously once a day at a dosage of approximately 13 ml per 100 kg of body weight for 3-5 days. The use in newborn foals is not recommended.
Dogs and Cats: It is administered intramuscularly or subcutaneously, initially twice a day, with a dosage of 0.4 ml per 5 kg of body weight, once a day for 3-5 days.
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