GENTAJECT 50 VETERINARY

NAME OF THE VETERINARY MEDICINAL PRODUCT

Gentaject 50 Veterinary, 50 mg/ml solution for injection for cattle, pigs, dogs, cats and ornamental birds.

Gentamicin (as gentamicin sulphate).

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml of solution for injection contains:

Active substance(s):

Gentamicin sulphate 85.0 mg
(equivalent to 50.0 mg gentamicin)

Excipients, the knowledge of which is necessary for the proper administration of the product:

Methyl parahydroxybenzoate 1.0 mg
Propylparahydroxybenzoate 0.1 mg
Sodium metabisulphite (Ph.Eur.) 1.6 mg

Propylene glycol, sodium citrate dehydrate, water for injections

INDICATION(S)

For cattle, pigs, dogs, cats and ornamental birds in the following infections with pathogens susceptible to gentamicin:

- respiratory tract infections
- digestive tract infections
- urogenital tract infections

Gentaject 50 Veterinary should be used taking into account the results of susceptibility testing.

CONTRAINDICATIONS

Do not use in animals with kidney and liver dysfunction and impaired hearing and balance.
Do not use concurrently with strong diuretics and potentially nephrotoxic drugs.

Do not use in pregnancy or in newly born animals.

Simultaneous treatment with muscle relaxants without prior dose reduction is contraindicated.

Do not use concurrently with muscle-relaxing agents such as anesthetics, barbiturates or polymyxins.

Do not use in cases of known hypersensitivity to gentamicin or other aminoglycosides, the possibility of cross-allergy with other aminoglycosides should be taken into account.

Do not use in case of hypersensitivity to any of the other ingredients.

Do not combine with other aminoglycoside antibiotics or antibiotics with bacteriostatic action.

ADVERSE REACTIONS

Because of the high systemic availability after intramuscular, subcutaneous or intravenous injection of gentamicin sulfate, frequent occurrence of side effects is to be expected, especially if the duration of use is longer than intended:

Disorders of the sense of hearing and balance and increased intensity of neuromuscular blockages are to be expected.

Nephrotoxic symptoms may occur depending on the dose and duration of treatment.

Allergic reactions (skin reactions, immediate anaphylactic reactions) rarely occur after parenteral administration of gentamicin; cross-allergy to other aminoglycoside antibiotics must be expected.

In case of side effects or allergic reactions, treatment should be discontinued immediately and the attending veterinarian must be notified. Treatment of the animal should be symptomatic:

The neuromuscular blocking properties of gentamicin sulfate, which can lead to seizures, respiratory paralysis and collapse, can be partially antagonized by calcium administration.

In case of anaphylactic shock: epinephrine (adrenaline) and glucocorticoids i.v.

In case of allergic skin reactions: antihistamines and/or glucocorticoids.

If you notice any side effects in your animal, especially any not listed in the package leaflet, inform your veterinarian or pharmacist.

TARGET SPECIES

Cattle, pigs, dogs, cats and ornamental birds.

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle:	for intramuscular use
Pigs:	for intramuscular use
Dogs, cats:	for subcutaneous, intramuscular or slow intravenous use
Ornamental birds:	for intramuscular use

Species	Administration route subcutaneous (s.c.) intramuscular (i.m.) intravenous (i.v.)	mg gentamicin per kg body weight	Frequency	Duration of treatment in days
Cattle	i.m.	2 mg/kg equivalent to 1 ml/25 kg	2x daily	3
Pigs	i.m.	2 mg/kg equivalent to 1 ml/25 kg		3
Dogs/ cats	s.c., i.m., slow i.v.	2-5 mg/kg equivalent to 0.25-1 ml/10 kg		3 to 5

Do not administer more than 1 ml per injection site in pigs.

Repeated injections should be administered at different injection sites.

Ornamental birds (species)	Administration route intramuscular (i.m.)	mg gentamicin per kg body weight	Frequency	Duration of treatment in days
Macaws – light red macaw	i.m.	2.5 mg/kg	2x daily	3 to 5
blue macaw	i.m.	10 mg/kg		
golden macaw	i.m.	10 mg/kg		
Beos	i.m.	5 mg/kg	6x daily	
Falcon/owl/ eagle	i.m.	2.5 mg/kg	3x daily	
Gray parrots	i.m.	10 mg/kg	3x daily	
Cockatiels	i.m.	5-10 mg/kg	2x daily	
Budgies	i.m.	4 mg/kg	3x daily	
Other parrots and parakeets	i.m.	5-10 mg/kg	2-5x daily	
Pheasants/ cranes	i.m.	5 mg/kg	3x daily	5 to 10

If the recommended duration of treatment has to be exceeded, kidney function should be monitored.
If the clinical condition does not improve significantly after 3 days of treatment, treatment should be modified.

ADVICE ON CORRECT ADMINISTRATION
See "Special warnings".

WITHDRAWAL PERIOD
Repeated treatments during the withdrawal period should be avoided due to accumulation of gentamicin in the liver, kidneys and at the injection site.

Cattle, intramuscular use:
Edible tissues: 192 days
Milk: 7 days
Pigs, intramuscular use:
Edible tissues: 146 days
Note: Ornamental birds are animals that are not intended for food production.

SPECIAL STORAGE PRECAUTIONS
Do not store above 25°C.
Shelf life after first opening of the vial: 28 days. Any remaining veterinary medicinal product should be discarded after the expiry of the shelf life after opening.
Do not use the veterinary medicinal product after the expiry date which is stated on the vial and the outer packaging.

SPECIAL WARNINGS
Interactions
The simultaneous administration of ototoxic, nephrotoxic and neuromuscular blocking drugs should be avoided.
Phenobarbital, isoflurane and muscle relaxants increase the neuromuscular blocking effect of gentamicin.
Furosemide and potent diuretics increase gentamicin toxicity. With regard to the antibacterial effect, there is a potential antagonism of aminoglycoside antibiotics and chemotherapeutic agents with rapid onset of bacteriostatic action.

Special precautions for use in animals
Slow administration should be ensured for intravenous administration.
Before initiating gentamicin therapy, the fluid balance must be adjusted. Adequate water supply should be ensured.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of known or suspected hypersensitivity to gentamicin and to avoid sensitization or contact dermatitis, direct skin contact or mucosal contact should be avoided when using Gentaject 50 Veterinary.
In the event of skin or mucous membrane contact, the product should be washed off under running water.

Overdose (symptoms, emergency measures and antidotes)
Overdosing or rapid intravenous injection can lead to respiratory paralysis and circulatory depression. This can be partially antagonized if neostigmine and calcium are rapidly administered intravenously. Oral administration of activated carbon can accelerate the elimination of gentamicin from the circulatory system.

Use during pregnancy, lactation or lay
The use of Gentaject 50 Veterinary during pregnancy is contraindicated due to possible damaging effects to the fetus. Because gentamicin crosses the placenta, as with other aminoglycoside antibiotics, oto- or nephrotoxic effects during prenatal development cannot be excluded.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
Any unused veterinary medicinal product should preferably be taken to a waste disposal sites. When it is disposed of with household waste, it must be ensured that there is no improper access to this waste. Veterinary medicinal products must not be disposed of via wastewater or the sewage system.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED
June 2018

OTHER INFORMATION
Pack sizes
Injection vial with 50 ml solution for injection.
Injection vial with 100 ml solution for injection.
Injection vial with 250 ml solution for injection.

Not all pack sizes may be marketed.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
Eurovet Animal Health BV
Handelsweg 25
NL-5531 AE Bladel

Distributor:
Dechra Veterinary Products Deutschland GmbH
Hauptstr. 6-8
88326 Aulendorf