Gentacin

85 mg/ml, solution for injection

for horses, cattle, calves, pigs, piglets, weaners, dogs and cats

Active ingredient: Gentamicin sulphate

Name and address of the marketing authorisation holder:
bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

Name of the veterinary medicinal product:
Gentacin; 85 mg/ml, solution for injection
for horses, cattle, calves, pigs, piglets, weaners, dogs and cats.
Active ingredient: Gentamicin sulphate

Statement of the active substance(s) and other ingredient(s):
1.0 ml solution for injection contains:
Pharmacological active substance:

Gentamicin sulphate	85.0 mg

(equivalent to 57.800 I.U. Gentamicin at an activity of 680 IU/mg Gentamicin sulphate)
Excipient, knowledge of which is essential for proper administration of the veterinary medicinal product:

Methyl parahydroxybenzoate	0.9 mg
Propyl parahydroxybenzoate	0.1 mg
Sodium metabisulfite	1.6 mg

Clear, colourless to slightly yellow solution for injection.

Indications:
For therapy of the following diseases caused by germs sensitive to gentamicin:

- *Cattle:*
  infections of the genital tract.
- *Calf:*
  infections of the respiratory tract, infections of the gastro-intestinal tract, septicaemia, infections of the joints, infections of the auditory meatus.
- *Pig:*
  infections of the respiratory tract, MMA complex.
- *Piglet, weaner:*
  infections of the respiratory tract, enzootic pneumonia, infections caused by *E. coli*.
- *Horse:*
  for the treatment of infections of the lower respiratory tract in horses caused by aerobic Gram-negative bacteria susceptible to gentamicin.
- *Dog, cat:*
  infections of the respiratory tract, infections of the gastro-intestinal tract, infections of the kidneys, the urinary and the genital tract, septicaemia, infections of the auditory meatus.

Contraindications:
Any use in pregnant animals requires strict indications.
Do not use in animals with impaired renal function or disturbances of the equilibrium or auditory tract.
Do not use concomitantly with strong diuretics or potential nephrotoxic drugs.
When used simultaneously with paralysing pharmaceuticals, do not inject intravenously or intra-abdominal.
Because of the danger of an acute renal failure do not use in exsiccotic animals.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Do not use concomitantly with bacteriostatic antibiotics.
Do not exceed the proposed dosing regimen.
Not authorised for use in horses producing meat or milk for human consumption.

Adverse reactions:
Disturbances of the auditory or balance function and the kidneys may occur when administered for a longer treatment period than indicated. Renal damage is expressed as proteinuria with an increase in nonprotein nitrogen in the blood.

Target species:
Horse (non-food producing horse), cattle, calf, pig, piglet, weaner, dog and cat.

Dosage for each species, route(s) and method of administration:

For slow intravenous use in horses.

- *Horse:*
  Intravenous administered single daily dose of 6,6 mg gentamicin (= 11.2 mg of gentamicin sulfate) per kg body weight corresponding to 6,6 ml injection solution per 50 kg body weight on 3-5 consecutive days.
  To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under- or over-dosing. The dosing regimen must not be exceeded.
  The use of gentamicin in foals and neonates is not recommended.

For intramuscular or slow intravenous injection in cattle and pigs.

- *Cattle, pig:*
  5.9 mg gentamicin sulphate (= 4000 IU gentamicin) per kg b.w.
  equivalent to 3.5 ml Gentacin / 50 kg body weight
- *Calves, weaner, piglets* in the first months of life:
  Initial treatment:
  5.9 mg gentamicin sulphate (= 4000 IU gentamicin) per kg b.w.
  equivalent to 0.7 ml Gentacin / 10 kg body weight
  Second and further injections:
  2.9 mg gentamicin sulphate (= 2000 IU gentamicin) per kg b.w.
  equivalent to 0.3 ml Gentacin / 10 kg body weight
  given twice daily in intervals of 12 hours for 3 to 5 days.

In pigs do not administer more than 1 ml per injection site.
Repeated injections should be made at different injection sites.

For intramuscular, subcutaneous or slow intravenous injection in dogs and cats.

- *Dogs* aged more than two weeks:
  6.5 mg gentamicin sulphate (= 4412 IU gentamicin) per kg b.w.
  equivalent to 0.8 ml Gentacin / 10 kg body weight
- *Dogs* younger than 2 weeks:
  Initial treatment:
  6.5 mg gentamicin sulphate (= 4412 IU gentamicin) per kg b.w.
  corresponding to 0.23 ml Gentacin / 3 kg body weight
  Second and further injections:
  3.25 mg gentamicin sulphate (= 2206 IU gentamicin) per kg b.w.
  corresponding to 0.12 ml Gentacin / 3 kg body weight
  given twice daily in intervals of 12 hours at the first days, thereafter once daily in intervals of 24 hours for 3 to 10 days.
- *Cats* aged more than two weeks:
  4.32 mg gentamicin sulphate (= 2941 IU gentamicin) per kg b.w.
  corresponding to 0.25 ml Gentacin / 5 kg body weight
- *Cats* younger than 2 weeks:
  Initial treatment:
  4.32 mg gentamicin sulphate (= 2941 IU gentamicin) per kg b.w.
  corresponding to 0.13 ml Gentacin / 2.5 kg body weight
  Second and further injections:
  2.16 mg gentamicin sulphate (= 1471 IU gentamicin) per kg b.w.
  corresponding to 0.06 ml Gentacin / 2.5 kg body weight
  given twice daily in intervals of 12 hours for 3 to 10 days.

If there is no clinical improvement after three days of treatment, diagnosis should be reconsidered and possibly a change of therapy is indicated.
If, under circumstances, a longer period of treatment is necessary and the sensitivity of the germs is confirmed, on account of the possible renal damage a regular kidney function test must be executed.

Advice on correct administration:
See above (method of administration).

Withdrawal period(s):
Following intramuscular or intravenous injection:

Pig, piglet, weaner:	edible tissues:	146 days
Calf:	edible tissues:	192 days
Cattle:	edible tissues:	214 days
	milk:	7 days

Due to accumulation of gentamicin in liver, kidneys and injection site, any repeated course of treatment during the withdrawal period must be avoided.
Not authorised for use in horses producing meat or milk for human consumption.

Special storage precautions:
Following opening store at a temperature not exceeding 25 °C. Shelf life after first opening the container: 14 days. Residual amounts remaining in the vial must be wasted 14 days after opening. Do not use after the expiration date stated on the label and the outer packaging.
Keep out of reach of children.

Special warnings:

Special warnings for each target species

Not indicated.

Special precautions for the use

Special precautions for the use in animals

Because of the small therapeutic range of gentamicin, an exact dose based on the body weight is to be calculated.
Gentacin should be used under consideration of an antibiogram.
Because of the danger of neuromuscular blockages the intravenous injection of Gentacin must be executed very slowly.
The use of Gentacin requires strict indications.
In dehydrated animals prior to therapy the fluid balance must be restored.

· *Horses:*

Gentamicin is well known to induce nephrotoxicity even at therapeutic doses. There are also isolated reports of ototoxicity with gentamicin. No margin of safety has been established under the approved dosing regimen. As such, gentamicin has a narrow margin of safety. The product should therefore only be used based on the benefit-risk assessment by the responsible veterinary surgeon for each individual horse, taking into account alternative available treatment.
In order to reduce the nephrotoxic risk, adequate hydration of animals under treatment should be ensured, and fluid therapy should be instituted, if required.
Close monitoring of horses being treated with gentamicin is strongly advised. This monitoring includes assessing relevant kidney parameters in blood (e.g. creatinine and urea) and urinalysis (e.g. gamma glutamyl transferase/creatinine ratio). Therapeutic blood monitoring of gentamicin concentration is also recommended because of known individual animal variations in peak and trough gentamicin plasma concentrations. Where blood monitoring is available, target peak plasma gentamicin concentrations should be approximately 16–20 µg/ml.
Particular caution should be taken when administering gentamicin with other potential nephrotoxic medicinal products (containing e.g. NSAIDs, furosemide, and other aminoglycosides).
Safety of gentamicin has not been established in foals and there is a lack of knowledge of the extra effects of gentamicin on foal kidneys, especially neonates. Current knowledge suggests that foals, especially neonates, are at a higher risk of gentamicin-induced nephrotoxicity compared to adults. Differences between neonatal foal kidneys and adults include a slower clearance of gentamicin in foals. As such, no margin of safety has been established in neonatal foals. It is therefore not recommended to use the product in foals.
Whenever possible, use of the product should be based on susceptibility testing of the bacteria isolated from the animal. Gentamicin is a narrow-spectrum Gram-negative bactericidal antimicrobial, without effects on anaerobe bacteria and mycoplasmas. Gentamicin does not penetrate intracellularly, or into abscesses. Gentamicin is de-activated in the presence of inflammatory debris, low oxygen environments and low pH.
The dosing regimen must not be exceeded. Use of the product deviating from the instructions given in the SPC increases the risk of nephrotoxicity, and may increase the prevalence of bacteria resistant to gentamicin. Extra caution is advised if using gentamicin in old horses, or with fever, endotoxemia, sepsis and dehydration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
User with known hypersensitivity to gentamicin must avoid the direct contact with the skin or mucous membranes.

Use during pregnancy, lactation or lay
The use during pregnancy requires strict indication.
The safety in pregnant horses is unknown. However, studies in laboratory animals have shown evidence of fetal nephrotoxicity. Use only based on the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
Gentamicin increases neuromuscular blockage.
When treating simultaneously with other pharmaceuticals, they should always be administered separately to avoid possible inactivation.
Do not use concomitantly with other oto- or nephrotoxic drugs.
Combined therapy with suitable antibiotics (e.g. ß-lactam antibiotics) may lead to a synergistic effect. Synergistic effects with acylaminopenicillins on *Pseudomonas aeruginosa* and with cephalosporins on *Klebsiella pneumoniae* have been described.
Within the group of aminoglycosides a complete cross-resistance is often observed. Please note that cross allergy to other aminoglycoside antibiotics may occur.

Overdose (symptoms, emergency procedures, antidotes)
Overdosage as well as a rapid intravenous injection may lead to neuromuscular blockage with convulsions, respiratory distress and circulatory depression. On the incidence of neuromuscular blockage, which lead to convulsions, respiratory distress and collapse, the drug must be withdrawn immediately. Inject calcium or neostigmin, if necessary.
In allergic or anaphylactic reactions, the pharmaceutical must be withdrawn instantly and a therapy with epinephrine, antihistaminics, and /or glucocorticoids is to be initiated.
Due to the oto- and nephrotoxic potential of gentamicin corresponding symptoms may occur following overdosage. The immediate withdrawal of the drug is necessary.

Incompatibilities
Incompatibilities exist to amphotericin, heparin, sulfadiazine, various penicillins and cephalosporins, chloramphenicol hydrogensuccinate sodium, oxacillin, vitamin B-complex. Mixtures with other pharmaceuticals are to be avoided because of the danger of possible incompatibilities.

Special precautions for the disposal of unused product or waste materials:
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with waste water or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

Date on which the package leaflet was last approved: 25.04.2019

Other informations:
OP (1 x 100 ml), OP (6 x 100 ml), OP (12 x 100 ml), BP 6 x (1 x 100 ml), BP 12 x (1 x 100 ml), BP 8 x (6 x 100 ml), BP 4 x (12 x 100 ml). Not all packing sizes may be marketed.

Marketing authorisation number: 3463.00.00
For Veterinary use only. Available on prescription only!