Neomycinsulfat

1 000 mg/g, powder for oral administration with the feed, the drinking water or the drink

Active ingredient: neomycin sulfate

Target species: Calves, pigs, piglets, chickens (young hens, laying hens and breeders)




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

Composition:
1 g powder contains:
Pharmacological active substance:
Neomycin sulfate 1 g
(equivalent to neomycin 650 I.U./mg)

Pharmaceutical form:
Powder for oral administration with the feed, the drinking water or the drink
White to slightly yellowish powder

Pharmacotherapeutic group:
aminoglycosid antibiotic

Target species:
Calves, pigs, piglets, chickens (young hens, laying hens and *breeders)*.

Indications:
Treatment of enteritis caused by bacteria susceptible to neomycin (*E. coli, Salmonella* spp., *Campylobacter* spp.).

Contraindications:
- Resistance to neomycin, kanamycin, gentamicin and streptomycin.
- Do not use concomitantly with strong diuretics or potential nephrotoxic drugs.
- The concomitant use with muscle relaxants without a previous dose reduction is contraindicated.
- Do not combine with other aminoglycosid-antibiotics or antibiotics acting bacteriostatic.
- Do not use in animals hypersensitive to neomycin or another aminoglycosid antibiotic.
- Do not use orally in ruminating animals.
- Do not use in animals with dysfunction of liver or kidney and disturbances of the auditory or equilibral function.
- Do not use during gestation.

Adverse reactions:
Especially in animals with an impaired mucosa of the gastro-intestinal tract or when the powder is administered longer than indicated, disturbances of the auditory and equilibral function or the renal function as well as neuromuscular blockade may occur.
Neuromuscular blocking properties of neomycin, which may lead to cramps, respiratory distress and collapse, may be antagonized partly by administration of neostigmin or calcium.
Following multiple oral administration damages of the gastro-intestinal tract followed by diarrhoea and malabsorption have been observed.

Allergic reactions (skin reactions, anaphylactic shock) are possible. A cross resistance to other aminoglycosid antibiotics must be observed.

Dosage for each species, route(s) and method of administration:
For oral administration with the feed and/or the drinking water in *pigs* and *chickens*.
For oral administration with the drink in *calves*.
Calves, pigs, piglets:
10 mg Neomycinsulfat per kg body weight (b.w.) per day

Young hens, laying hens, breeders:
30 mg Neomycinsulfat per kg body weight (b.w.) per day

It has to be ensured that the designated dose is taken up completely.
In animals with obviously disturbed state of health and/or in animals showing inappetence, a preparation to be administered parenterally shall be preferred.

For the treatment of parts of stock (*chickens*):
Dissolve the needed amount of powder completely and every day fresh in a small part of water and add to drinking water.
The powder is to be mixed for each application fresh into the ready to use and cooled down milk substitute. Ensure a complete mixing and administer prior to the feeding.
The needed amount of powder must be mixed for each application freshly into a part of the food. Ensure a complete mixing and administer prior to the feeding. It has to be ensured that the designated dose is taken up completely.
To ensure an equable water intake by all animals to be treated, sufficient watering places have to be provided.
The dosage has to be adjusted to the actual, real daily intake of drinking water by the animals as this varies in dependence on the age, state of health, purpose of the animals and the way of rearing (e.g. varying ambient temperature, different light patterns).
For the above mentioned dose, the amount of Neomycinsulfat to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Pigs, piglets:

$$\frac{\text{10 mg Neomycinsulfat per kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal}} = \text{... mg Neomycinsulfat per l drinking water}$$

Chickens:

$$\frac{\text{30 mg Neomycinsulfat per kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal}} = \text{... mg Neomycinsulfat per l drinking water}$$

The duration of treatment is in general 3 days.
Continue the treatment for two more days after subsidence of clinical symptoms.
Should there be no significant improvement of the state of health after 3 days of treatment, review diagnosis and change therapy, if necessary.
In case of outdoor housing, the animals should be kept in the stable during the duration of treatment.

After conclusion of the treatment, the drinking equipment has to be cleaned thoroughly in a suitable manner to avoid the intake of subtherapeutic, especially resistance-causing residual amounts of the applied antibiotic.

Withdrawal period(s):

Pig, Calf:	edible tissues:	14 days
Chickens:	edible tissues:	7 days
	eggs:	0 days

Advice on correct administration:

Special precautions for use:

Special precautions for use in animals:

Neomycin shows only a small therapeutic range, therefore, to avoid overdosage, dosage according to body weight has to be strictly observed.

The application of Neomycin sulfate should be done considering a susceptibility testing.

Special safety precautions to be taken by the person administering the medicinal product to animals:

Avoid direct skin contact and inhalation during handling and application due to the risk of sensitisation or contact dermatitis. Wear a dust mask and gloves when handling the veterinary medicinal product.

Use during pregnancy, lactation or lay:

Neomycin passes the placenta and may show ototoxicity or nephrotoxicity in the fetus.
Do not use during gestation.

Interaction with other medicinal products and other forms of interaction:

Mixing with other drugs should be avoided due to possible incompatibilities.
When other pharmaceuticals are applied concomitantly, neomycin can possibly be inactivated.
Avoid the combination with chemotherapeutics acting bacteriostatic.
Do not use concomitantly with other oto- or nephrotoxic drugs.

Overdose:

The neuromuscular blocking properties of neomycin, which may lead to cramps, respiratory distress and collapse, may be antagonized partly by administration of neostigmin or calcium.
Allergic reactions (skin reactions, anaphylactic shock) are possible. A cross resistance to other aminoglycosid antibiotics must be observed.
On the incidence of adverse reactions, please withdraw the pharmaceutical immediately and treat symptomatically.
In anaphylactic shock: epinephrine (adrenalin) and glucocorticoids i.v./i.m.
In allergic skin reactions: antihistaminics and /or glucocorticoids.

Incompatibilities:

Due to possible incompatibilities, mixtures with other pharmaceuticals must be avoided.

Special storage precautions:

White HDPE round box: Do not store at temperatures exceeding 25 °C.
Keep out of reach and sight of children.
Shelf life after first opening the container: 7 days.

Residuals of the pharmaceutical remaining in the packing after ending of this period must be wasted.
Please keep the container well closed after withdrawal of part of its contents.
Stability of the medicated drinking water: 24 hours.
Stability of the medicated milk or milk substitute: 4 hours.
Solutions of the pharmaceutical in the milk/milk substitute must be prepared immediately prior to its use and are to be fed instantly.
Do not use after the expiration date stated on the label.

Special precautions for the disposal of unused veterinary medicinal product or waste materials, if any:
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: 15.12.2010

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For animal treatment only.

Available on prescription only!

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