Pyanosid® Solution

50/100 mg/ml solution for injection of cattle (calves), pigs, dogs and cats

Composition

1 ml solution for injection contains:

Active substance:

Lincomycin hydrochloride-monohydrat equivalent to 50 mg Lincomycin	56,70 mg
Spectinomycin sulfate-tetrahydrate equivalent to 100 mg Spectinomycin	151,20 mg

Excipients:

Benzyl alcohol	9,45 mg
Sodium hydroxide solution 10%	
Hydrochloric acid 10%	
Water for injection	

Clear, colourless solution for injection.

Available on prescription only!

MAH-No.: 13076.00.00

Target species

Cattle (calf), pig, dog, cat

Indication for use for each target species

Therapy of the following diseases caused by germs sensitive to lincomycin and spectinomycin:

- Pig:
  Mycoplasma infections (enzootic pneumonia).
  Swine dysentery caused by *Brachyspira hyodysenteriae* and complicated by concomitant enteric bacterial infections (e.g. *Escherichia coli* and *Campylobacter* spp.).
  Elimination of the pathogens mentioned, in particular the zoonotic pathogens involved (e.g. *Campylobacter jejuni / Escherichia coli*), is not part of the therapeutic claim of the veterinary medicinal product.
- Cattle (Calf):
  Treatment of infections of the respiratory tract and gastro-intestinal tract in calves without a functional ruminal flora.
- Dog:
  Infections of the respiratory tract (pneumonia, pharyngitis, tonsillitis, laryngitis, bronchitis), purulent skin inflammations (pyogenic and pustular dermatitis), abscesses, bladder and uterine inflammation (cystitis, metritis).
- Cat:
  Infections of the respiratory tract, infected wounds and abscesses, cystitis.

Containdications

Do not use in case of hypersensitivity to spectinomycin, lincomycin or clindamycin.
Do not use in horses, rabbits, hamsters and ruminating animals (risk of severe colitis).

Special warnings
Do not use concomitantly with anaesthetics or agents with a neuromuscular blocking effect.
In rare cases, respiratory arrest may occur in connection with anaesthesia (barbiturates).

Special precautions for use:
Special precautions for safe use in the target species:
The veterinary medicinal product should be used in consideration of an antibiogram.
Due to the presence of very high resistance rates to lincomycin and spectinomycin, treatment using the veterinary medicinal product should only be carried out after the susceptibility of *Brachyspira hyodysenteriae* and the laboratory-diagnosed pathogens of the accompanying dysentery flora (e.g. commensals such as *Escherichia coli* or *Campylobacter* spp.) has been proven.
In pig herds in particular, the pathogen situation and treatment options for herd problems such as dysentery or pneumonia must be considered in a complex manner.
In the affected farms, efforts should be made to avoid routine repeated use of the veterinary medicinal product by optimising farm management, e.g. in animal husbandry and hygiene measures. Herd reorganisation should be considered.
When using spectinomycin, resistance rates and superinfections with resistant germs must be expected.
The withdrawal of single doses from the injection bottle should be carried out under aseptic conditions. The injection needle or syringe should therefore be cleaned and disinfected.
If renal function is impaired, the dose should be reduced or the dose interval extended.
The veterinary medicinal product should not be used in the presence of liver dysfunction.
Do not use in neonates due to possible toxic effects.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Direct contact via the user's skin or mucous membranes should be avoided due to the risk of sensitisation.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Lincomycin and spectinomycin have not shown embryotoxic or teratogenic effects.
In lactating animals, lincomycin is also excreted with the milk. Particular care should be taken when using the preparation in lactating animals, as possible gastrointestinal side effects of lincomycin and spectinomycin may occur in suckling puppies or piglets.

Interaction with other medicinal products and other forms of interaction:
There is complete cross-resistance between lincosamides (lincomycin and clindamycin) and partial cross-resistance to macrolide antibiotics such as erythromycin, kitasamycin, spiramycin and tilmicosin.
Due to in vitro incompatibilities of lincomycin with penicillins and kanamycin, mixing with other medicinal products should be avoided. There is a clear antagonism between lincomycin and erythromycin. Due to the identical site of action in bacterial metabolism, concomitant use with other macrolide antibiotics is not advisable.

If anaesthetics or agents with neuromuscular blocking effects (e.g. tubocurarine, gallamine, pancuronium) are used at the same time, lincomycin increases the curare-like effects of these muscle relaxants.

Overdose:
Neuromuscular blockade, which cannot be reversed by indirectly acting parasympathomimetics (e.g. neostigmine) and can only be partially reversed by calcium, may occur in individual cases.
Immediate discontinuation of therapy and emergency measures (see under "Side effects") according to the symptoms. No specific antidote is known.

Major incompatibilities:
Due to in vitro incompatibilities of lincomycin with penicillin and kanamycin, mixing with other medicinal products should be avoided.

Adverse events
Target species: Cattle (calf), pig, dog, cat:

Uncommon (1 to 10 animals / 1,000 animals treated):	Diarrhoea [1,2] vomiting [1] anorexia [1]
Rare (1 to 10 animals / 10,000 animals treated):	Reddening of the skin [1] Restlessness [1] Allergic Reaction [3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neuromuscular disorder [4] Agranulocytosis, leucopenia, thrombocytopenia Increase in aspartate aminotransferase (AST) Influence on the conduction velocity in the heart, hypotension
Undetermined frequency (cannot be estimated based on available data):	Reddening of the skin [3,5] swelling [3,5] Irritation at the injection site [6] Disturbance of the digestive tract [7]

[1] due to lincomycin
[2] intensification if diarrhoea is already present, in these cases a discontinuation/change of therapy is indicated
[3] pig
[4] Not reversed by indirectly acting parasympathomimetics (e.g. neostigmine). Only partially cancelled by calcium.
[5] of the vulva and anal region. 18 to 36 hours after the start of treatment. Relieves on its own over the course of five to seven days of treatment.
[6] minor after intramuscular injection
[7] If occurring shortly after starting treatment, discontinuation/change of therapy is indicated

If allergic reactions occur, the veterinary medicinal product should be discontinued immediately and treated symptomatically:
- In case of anaphylactic shock: Epinephrine (adrenaline) and glucocorticoids i.v..
- In case of allergic skin reactions: Antihistamines and/or glucocorticoids.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

Dosage for each target species, route and duration of administration
For intramuscular injection.

- Pig:
1 ml / 10 kg body weight (equivalent to 5 mg lincomycin and 10 mg spectinomycin / kg b.w.) by intramuscular injection. The dose may be repeated at intervals of 24 hours for 3 to 7 consecutive days.

- Cattle (calf):
1 ml / 10 kg b.w. (equivalent to 5 mg lincomycin and 10 mg spectinomycin / kg b.w.) by intramuscular injection. The dose is to be injected twice on the first day of treatment and once daily the following 2 to 4 days.

- Dog und cat:
1 ml / 5 kg b.w. (equivalent to 10 mg lincomycin and 20 mg spectinomycin / kg b.w.) once or twice daily by intramuscular injection. The injection may be repeated at intervals of 12 - 24 hours for 3 to 7 consecutive days.

Duration of treatment:

Cattle (calf):	3 - 4 days
Pig:	3 - 7 days
Dog and cat:	3 - 7 days

If there is no clear improvement in the condition after 3 days of treatment, the diagnosis should be reviewed and the therapy changed if necessary.

Instructions for correct use
See section “Dosage for each target species, route and duration of administration”.

Withdrawal periods
Cattle (calf), pig: Edible tissues: 21 days

Special storage precautions
Keep out of the sight and reach of children.
Do not store above 25 °C. Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp.. The expiry date refers to the last day of that month.
Shelf life after first opening of the primary packaging: 7 days.
Any residues of the medicinal product remaining in the container must be discarded after the expiry date after opening.

Special precautions for disposal
Unused veterinary medicinal products should preferably be disposed of at hazardous waste collection centres. If disposed of together with household waste, it must be ensured that this waste cannot be misused. Veterinary medicinal products must not be disposed of with waste water or via the sewage system. Local regulations for the disposal of pharmaceuticals have to be observed.

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

Marketing authorisation numbers and packaging
13076.00.00

Packaging sizes:
50 ml or 100 ml brown glass vial type I with bromobutyl rubber stopper and flanged aluminium cap

Packaging sizes original packaging:
Outer carton with 1 brown glass vial with 50 ml solution for injection
Outer carton with 6 brown glass vials with 50 ml solution for injection
Outer carton with 12 brown glass vials with 50 ml solution for injection
Outer carton with 1 brown glass vial with 100 ml solution for injection
Outer carton with 6 brown glass vials with 100 ml solution for injection
Outer carton with 12 brown glass vials with 100 ml solution for injection

Packaging sizes bundle packaging:
Outer carton with 6 brown glass vials with 50 ml solution for injection
Outer carton with 12 brown glass vials with 50 ml solution for injection
Outer carton with 8 bundles of 6 brown glass vials each with 50 ml solution for injection
Outer carton with 4 bundles of 12 brown glass vials each with 50 ml solution for injection
Outer carton with 6 brown glass vials with 100 ml solution for injection
Outer carton with 12 brown glass vials with 100 ml solution for injection
Outer carton with 8 bundles of 6 brown glass vials each with 100 ml solution for injection
Outer carton with 4 bundles of 12 brown glass vials each with 100 ml solution for injection

Not all pack sizes may be marketed.

Date of last revision of the package leaflet
23/04/2024.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).