

Pyanosid® Solution

50/100 mg/ml solution for injectione

for cattle (calves), pigs, dogs and cats,

Active ingredients: Lincomycin in form of Lincomycin hydrochloride monohydrate and Spectinomycin in form of spectinomycin sulphate tetrahydrate

Target species: cattle (calves), pigs, dogs and cats



Name and address of the marketing authorisation holder:

bela-pharm GmbH & Co. KG, Lohner Str. 19, 49377 Verchta - Germany

Composition:

1 ml solution contains:

Pharmacological active substance:

Lincomycin hydrochloride monohydrate 56.70 mg
equivalent to 50 mg lincomycin

Spectinomycin sulphate 4 H₂O 151.20 mg
equivalent to 100 mg spectinomycin

Adjuvants:

Benzyl alcohol 9.45 mg

Pharmaceutical form:

Solution for intramuscular injection.

Clear, colourless solution.

Pharmacotherapeutic group:

antibiotic

Package size:

50 ml, 100 ml

Target species:

Calves, pigs, dogs and cats

Indications:

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

Pig:

Treatment of infections of the respiratory tract caused by *Mycoplasma spp.* (enzootic pneumonia).

Therapy of swine dysentery caused by lincomycin-sensitive *Brachyspira hyodysenteriae* complicated by concomitant intestinal flora (e.g. commensals like *E. coli* or *Campylobacter spp.*).

The elimination of the bacteria stated, especially of the concomitant zoonotic germs (*Campylobacter jejuni*, *E. coli*) is not part of the therapeutic claim of Pyanosid® Solution.

Calves:

Treatment of infections of the respiratory tract and gastro-intestinal tract in *calves* without a functional ruminal flora.

Pyanosid® Solution

Dogs:

Treatment of infections of the respiratory tract (pneumonia, pharyngitis, tonsillitis, laryngitis, bronchitis), purulent inflammations of the skin, (pyogenic and pustular dermatitis), abscesses, inflammations of the bladder and uterus (cystitis, metritis).

Cats:

Treatment of infections of the upper respiratory tract, infected wounds and abscesses, inflammation of the bladder (cystitis).

Contraindications:

Known hypersensitivity to spectinomycin, lincomycin and clindamycin.

Do not administer to *horses, rabbits, hamsters*, and animals with a functional rumen, as severe colitis may occur.

The dose must be reduced or dosage intervals must be prolonged in presence of restricted renal function.

Do not administer Pyanosid® Solution in presence of liver dysfunction.

Because of possible toxic effects do not use in newborn animals.

Adverse reactions:

Diarrhoea, vomiting and anorexia may appear occasionally after administration of lincomycin, whereas reddening of the skin and restlessness rarely occurs.

The treatment should be discontinued or changed, respectively, if gastrointestinal disorders or an intensification of already existing diarrhoea occur shortly after starting the therapy.

Slight redness and swellings of the anal and vulvar region may appear 18 to 36 hours after starting the treatment in pigs. These symptoms disappear again during the course of the 5- to 7-day treatment.

Allergic reactions are rare.

Neuromuscular blocks may occur in single cases which are not cancelled through indirectly active parasympathomimetic drugs (e.g. neostigmine) and only partially cancelled by administration of calcium.

The intramuscular application may cause slight local irritations. In addition agranulocytosis, leucopenia, thrombocytopenia, increase in AST activity in the serum, influencing of the conduction velocity in the heart as well as hypotension were observed in single cases.

In case of anaphylaxis withdraw the pharmaceutical immediately and treat symptomatically.

In anaphylaxis: adrenaline and/or glucocorticoids i.v./i.m.

In the presence of allergic skin reactions: antihistaminic agents and/or glucocorticoids.

Dosage for each species, route and method of administration:

For intramuscular injection.

Pigs:

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.

Calves:

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.

Pyanosid® Solution

Dogs and cats:

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:

Calves: 3 - 4 days

Pigs: 3 - 7 days

Dogs and cats: 3 - 7 days

Should there be no significant improvement of the pathological state after 3 days of treatment, review the diagnosis and change the therapy, if necessary.

Withdrawal period (s):

Pig, calf: edible tissues: 21 days

Special warnings:

Special warnings for each target species:

Do not use concomitantly with anaesthetics or agents with a neuromuscular blocking activity.

Special precautions for use:

Special precautions for use in animals:

The application of Pyanosid® Solution should be based on the results of an antimicrobial sensitivity test.

On account of the high resistance rates to lincomycin and spectinomycin, treatment with Pyanosid Solution should only be performed after proving the susceptibility of *Brachyspira hyodysenteriae* and the germs of the dysentery concomitant flora (e.g. commensals like *E. coli* or *Campylobacter spp.*), determined by laboratory diagnostics.

Especially in pig farms the contamination situation and possibilities of treatment of specific problems like *swine* dysentery or enzootic pneumonia shall be considered in a complex way. In the farms concerned, the repetitive use of Pyanosid® Solution as a matter of routine shall be avoided by optimising the farm's management (animal keeping and sanitary measures). Consider a reorganisation of stock.

High resistance rates as well as superinfections with resistant germs are to be expected during the treatment with spectinomycin.

By withdrawing single doses from the vial avoid a contamination by using cleaned and sterilized needles and syringes.

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

Avoid the direct contact with skin or mucous membranes to reduce the risk of sensitisation.

Use during pregnancy, lactation or lay:

Lincomycin and spectinomycin have not shown embryotoxic or teratogenic effects. In lactating animals lincomycin is excreted by the milk as well. Therefore special care is required with regard to the application of Pyanosid® Solution in lactating animals as gastrointestinal side effects of lincomycin and spectinomycin may appear in *suckling* puppies and piglets.

Pyanosid® Solution

Interaction with other medicinal products and other forms of interaction:

There is a complete cross-resistance between lincosamides (lincomycin and clindamycin) and partial resistance to macrolide antibiotics such as erythromycin, kitasamycin, spiramycin and tilmicosin.

In-vitro incompatibilities of lincomycin with penicillin and kanamycin have been noticed.

Mixing with other drugs should therefore be avoided.

There is an obvious antagonism between lincomycin and erythromycin. Simultaneous treatment with other macrolide antibiotics is not useful due to the identical site of action in the bacterial metabolism.

When administered simultaneously with anaesthetics or agents with neuromuscular blocking action (e.g. tubocurarin, gallamin, pancuronium), lincomycin increases the curare-like effects of these muscle relaxants.

Warning:

In rare cases apnoea may occur in connection with barbiturate narcosis.

Overdose:

Neuromuscular blocks may occur in single cases which are not cancelled through indirectly active parasympathomimetic drugs (e.g. neostigmine) and only partially cancelled by administration of calcium.

Immediately discontinue the treatment and treat symptomatically (see under "Adverse reactions"). No specific antidote known.

Incompatibilities:

Mixing with other drugs should be avoided due to in vitro incompatibilities of lincomycin with penicillin and kanamycin.

Special storage precautions:

Do not store at temperatures exceeding 25 °C and protected from light.

Keep out of reach and sight of children.

Shelf life after first opening of the container: 7 days.

Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.

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 of revision of the text: 03.12.2009

Marketing authorisation number: 13076.00.00 (Germany)

For animal treatment only.

Available on prescription only!

K/12/09