Pyanosid Powder

227.52 / 455.73 mg/g; powder for oral administration

for pigs, poultry (broiler and parent stock)

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

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:
Pyanosid Powder. 227.52 / 455.73 mg/g; powder for oral administration
for pigs, poultry (broiler and parent stock).
Active ingredients: Lincomycin in form of Lincomycin hydrochloride monohydrate and Spectinomycin in form of spectinomycin sulphate tetrahydrate

Statement of the active substance(s) and other ingredient(s):
1 g powder contains:
Pharmacological active substance:

Lincomycin hydrochloride monohydrate equivalent to 227.52 mg lincomycin	258.01 mg
Spectinomycin sulfate, 4 H_2O equivalent to 455.73 mg spectinomycin	689.11 mg

White, fine powder.

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

· *Pigs:*
For the treatment and metaphylaxis of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis*, and associated enteric pathogens *(Escherichia coli)* susceptible to lincomycin and spectinomycin.
The presence of the disease in the group must be established before the product is used.

· *Chickens (broiler, parent stock):*
For the treatment and metaphylaxis of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to lincomycin and spectinomycin, and associated with a low mortality rate.
The presence of the disease in the flock must be established before the product is used.

Contraindications:
Do not administer to laying hens or young hens, which are intended to produce eggs for human consumption.
Resistance and hypersensitivity to clindamycin, lincomycin and spectinomycin.
Do not administer orally to ruminant animals, horses, hamsters, guinea pigs, rabbits and chinchillas.
The dose must be reduced or dosage intervals must be prolonged in presence of restricted renal function.
Do not administer Pyanosid Powder in presence of liver dysfunction.
Because of possible toxic reactions 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.
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.
Allergic reactions and 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.
In case of anaphylaxis: adrenaline and/or glucocorticoids i.v./i.m.;
in presence of allergic skin reactions: antihistaminic agents and/or glucocorticoids.

Target species: *Pigs, chickens (broiler, parent stock)*.

Dosage for each species, route(s) and method of administration:
For use in drinking water.
The recommended dose is as follows:

· *Pig:* 3.33 mg Lincomycin/kg body weight (b.w.)/day and
6.67 mg Spectinomycin/kg body weight (b.w.)/day
equivalent to: 14.6 mg Pyanosid Powder/kg b.w./day
Duration of treatment: 7 days.

The dosage has to be adjusted to the actual 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. different ambient temperature).
For the above mentioned dose, the amount of Pyanosid Powder to be mixed into the drinking water for the animals to be treated is to be calculated according to the following formula:

$$\frac{\text{14.6 mg Pyanosid Powder per kg b.w. / day} \times \text{average b.w. of the animals to be treated}}{\text{average daily uptake of drinking water (l) animal}} = \text{mg Pyanosid Powder per l drinking water}$$

The appropriate quantity of powder is to be dissolved freshly every day and completely in a small amount of water and to be added to the drinking water.
Pyanosid Powder is to be administered before the actual feeding due to the fact that the enteric absorption of active ingredients is reduced to the half if feed is taken in simultaneously.
Sufficient watering places are to be ensured in order to guarantee an even water uptake by all animals. In case of outdoor housing, the animals should be kept in the stables during the treatment.
Should there be no significant improvement of the pathological state after 3 days of treatment, review the diagnosis and change the therapy, if necessary.

Parenteral administration of the preparation is to be preferred in animals with clearly disturbed general condition and/or animals suffering from inappetence.
Upon completion of the treatment, the watering trough is to be cleaned in a suitable manner to avoid the intake of subtherapeutic, especially resistance-promoting residues of the applied antibiotic.

· *Chickens (broiler, parent stock):* 16.65 mg Lincomycin/kg body weight (b.w.)/day and 33.35 mg Spectinomycin/kg body weight (b.w.)/day equivalent to: 73.2 mg Pyanosid Powder/kg b.w./day
Duration of treatment: 7 days.

The dosage has to be adjusted to the actual 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. different ambient temperature).
For the above mentioned dose, the amount of Pyanosid Powder to be mixed into the drinking water for the animals to be treated is to be calculated according to the following formula:

$$\frac{\text{73.2 mg Pyanosid Powder per kg b.w. / day} \times \text{average b.w. of the animals to be treated}}{\text{average daily uptake of drinking water (l) animal}} = \text{mg Pyanosid Powder per l drinking water}$$

The appropriate quantity of powder is to be dissolved freshly every day and completely in a small amount of water and to be added to the drinking water.
Sufficient watering places are to be ensured in order to guarantee an even water uptake by all animals to be treated. In case of outdoor housing, the animals should be kept in the stables during the treatment.
Pyanosid Powder is to be administered before the actual feeding due to the fact that the enteric absorption of active ingredients is reduced to the half if feed is taken in simultaneously.
In stocks endangered by mycoplasmosis, the respective animals should obtain medicated drinking water only during the first 5 days of life. Repeat the treatment at the age of 4 weeks or at the time of vaccination, respectively.
Elder animals should get medicated drinking water at the time of vaccination upon first signs of disease.
Should there be no significant improvement of the pathological state after 3 days of treatment, review the diagnosis and change the therapy, if necessary.
Upon completion of the treatment, the watering trough is to be cleaned in a suitable manner to avoid the intake of subtherapeutic, especially resistance-promoting residues of the applied antibiotic.

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

Withdrawal periods:

Pig:	edible tissues:	8 days
Chicken (broiler, parent stock):	edible tissues:	8 days

Not authorised for use in birds producing eggs for human consumption, including replacement chicks, which are intended to produce eggs for human consumption.
Animals must not be slaughtered for human consumption during treatment.

Special storage precautions:
For this veterinary medicinal product no special storage conditions are required.
Shelf life after first opening the container: 60 days
Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.
Do not use after the expiration date stated on the label and the outer packaging.
The medicated drinking water has to be prepared freshly every day.
Keep out of reach of children.

Special warnings:
Special warnings for each target species
The oral administration of preparations containing lincomycin is indicated in pigs and chickens only. Lincomycin may cause severe gastrointestinal disorders in other animal species.
In *E. coli*, a significant part of the strains show high MIC values (minimum inhibitory concentrations) against the lincomycin-spectinomycin combination and may be clinically resistant, although no breakpoint is defined.
Due to technical constraints the susceptibility of *L. intracellularis* is difficult to test in vitro, and data about the lincomycin-spectinomycin resistance status in that species are lacking.

Special precautions for use
Special precautions for use in animals
Do not administer simultaneously with anaesthetics or active ingredients with neuromuscular blocking effect.
On account of a common resistance development, the sensitivity of mycoplasma and the secondary flora is to be tested before administering Pyanosid Powder to broilers and parent stock.
Very high resistance rates as well as superinfections with resistant germs are to be expected during the treatment with spectinomycin.
The elimination of the causative germs, especially of the concomitant zoonotic bacteria (e.g. *Campylobacter jejuni, E. coli*) is not part of the therapeutic claim of Pyanosid Powder.

Special safety precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid direct skin contact and inhalation due to the risk of sensitisation or contact dermatitis during handling and/or application. For this purpose, wear a dust mask and gloves.

Use during pregnancy, lactation or lay
Special care is required with regard to the application of Pyanosid Powder in lactating animals as gastrointestinal side effects of lincomycin may appear in very young (suckling) animals.

Interaction with other medicinal products and other forms of interaction
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.
The enteric absorption of lincomycin in the intestinal tract is reduced to about the half if feed is taken in simultaneously and deteriorates through kaolin or pectin.

During the simultaneous administration of anaesthetics or agents with neuromuscular blocking action (e.g. tubocurarin, gallamin, pancuronium), lincomycin increases the curare-like effects of these muscle relaxants.
Incompatibilities during the simultaneous administration of lincomycin and monensin cannot be precluded in poultry.
There is a complete cross-resistance between lincosamides (lincomycin and clindamycin) and partial resistance to macrolide antibiotics such as erythromycin, kitasamyin, spiramycin and tilmicosin.

Overdose (symptoms, emergency procedures, antidotes), if necessary
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, e.g. lincomycin shows in-vitro incompatibility with with penicillin and kanamycin.

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: 16.03.2017

Other informations:
OP (1 x 300 g), OP (1 x 1 kg), OP (1 x 3 kg),
BP 1 x (12 x 300 g), BP 1 x (12 x 1 kg).
Not all packing sizes may be marketed.