Lincobel S

226.8 mg/ml, solution for injection

Active ingredient: Lincomycin hydrochloride monohydrate

Target species: Pigs

Name and address of the marketing authorisation holder:

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

Composition:

1 ml solution contains:

Pharmacological active substance:

Lincomycin hydrochloride 1 H₂O 226.8 mg

equivalent to Lincomycin 200.0 mg

Adjuvants:

Benzyl alcohol 9.45 mg

Pharmaceutical form:

Solution for intramuscular injection Transparent to yellowish-brown solution.

Pharmacotherapeutic group:

Lincosamide antibiotic

Target species:

Pigs

Indications for use:

Treatment of infectious diseases in pigs caused by germs sensitive to Lincomycin: Acute and chronic infections of the respiratory tract, infections caused by *Mycoplasma* spp.

Contraindications:

Resistance and hypersensitivity to lincomycin.

Do not use in *horses*, *rabbits*, *hamsters*, *guinea pigs*, *chinchillas* and *ruminating animals*, because of possible incidence of severe colitis.

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

Adverse reactions:

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

Allergic reactions and neuromuscular blocking may occur in single cases.

The intramuscular injection may cause slight local irritation.

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.

The treatment should be discontinued or changed, respectively, if gastrointestinal disorders or an intensification of already existing diarrhoea occur shortly after starting the therapy. On the occurrence of adverse reactions, the application of the pharmaceutical has to be stopped immediately and symptomatic treatment must be initiated.







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In anaphylactic shock: epinephrine (adrenaline) and glucocorticoids intravenously;

In allergic skin reactions: antihistaminics and /or glucocorticoids.

A neuromuscular block may be partially released by administration of calcium. Indirect active parasympathomimetic drugs (e.g. neostigmine) are poorly or not effective.

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

for intramuscular injection.

Pig: 10.0 mg lincomycin hydrochloride monohydrate /kg body weight (b.w.) daily

equivalent to 0.9 ml Lincobel S / 20 kg b.w. per day.

Dosage interval: 24 hours

Reduce the dose in case of limited renal function or disturbances in liver metabolism. The duration of treatment is at least three days. Should there be no significant improvement of of the pathological state after three days of treatment, review the diagnosis and change therapy, if necessary.

Withdrawal period(s:)

Pig: edible tissues: 7 days

Advice on correct administration:

Special warnings for each target species:

Not indicated.

Special precautions for use:

Special precautions for use in animals:

Do not use concomitantly with anaesthetics or agents with a neuromuscular blocking activity. The application of lincomycin should be done under consideration of an antibiogram.

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:

In lactating animals, lincomycin is eliminated with the milk as well.

Special care has to be taken when using the pharmaceutical in lactating animals, as gastro-intestinal disturbances caused by lincomycin may occur in suckling off-spring.

Interaction with other medicinal products and other forms of interaction:

Due to the identical site of action in the bacterial metabolism, simultaneous application of other macrolide antibiotics is not advisable.

When administered concomitantly with anaesthetics or agents with a neuromuscular blocking activity, lincomycin increases the curare-like effect of these muscle relaxants.

Between lincomycin and clindamycin a complete cross-resistance and to macrolid-antibiotics as e.g. erythromycin, spiramycin, tilmicosin and tylosin a partial cross-resistance is observed.

Overdose:

See "adverse reactions".

Incompatibilities:

Mixing with other pharmaceuticals should be avoided due to possible incompatibilities.



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Special storage precautions:

After opening store at temperatures not exceeding 25 °C.

Keep out of reach and sight of children.

Shelf life after first opening of the container: 14 days.

Residuals of the pharmaceutical remaining in the packing after ending of this period must be wasted.

Do not use after the expiration date stated on the label.

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: 11.11.2010

Marketing authorisation number: 6932548.00.00 (Germany)

For animal treatment only.

Available on prescription only!

