

# Lincobel

113.4 mg/ml, solution for injection

Active ingredient: Lincomycin hydrochloride monohydrate

Target species: Pigs, dogs, cats

## Name and address of the marketing authorisation holder:

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

## Composition:

1 ml solution contains:

### Pharmacological active substance:

Lincomycin hydrochloride 1 H<sub>2</sub>O 113.4 mg  
(equivalent to Lincomycin 100.0 mg)

### Adjuvants:

Benzyl alcohol 9.45 mg

## Pharmaceutical form:

Solution for intramuscular injection.

Clear, colourless to very slightly brownish solution for injection.

**Pharmacotherapeutic group:** Lincosamide antibiotic.

**Target species:** *Pigs, dogs, cats*

## Indications for use:

Treatment of infectious diseases in *pigs* caused by germs sensitive to Lincomycin:

- acute and chronic infections of the respiratory tract,
- acute and chronic dermatitis and wound infections,
- metritis,
- arthritis,
- infections caused by *Mycoplasma* spp.,
- swine dysentery.

Treatment of infectious diseases in *dogs* and *cats* caused by germs sensitive to Lincomycin:

- acute and chronic dermatitis and wound infections,
- metritis,
- infections caused by *Mycoplasma* spp.

## Contraindications:

Resistance and hypersensitivity to lincomycin.

Reduce the dose or prolong the dosage intervals in case of reduced renal function.

Do not administer in case of hepatic dysfunction.

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

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

## Adverse reactions:

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

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 of their own within the treatment period of 5 to 7 days.

Allergic reactions are rare.

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

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.

On the occurrence of allergic reactions, the application of the pharmaceutical has to be stopped immediately and symptomatic treatment must be initiated.

In anaphylactic shock: epinephrine (adrenaline) and glucocorticoids;

In allergic skin reactions: antihistaminics and /or glucocorticoids.

### **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 0.1 ml Lincobel / kg b.w. per day.

*Dog:* 20.0 mg lincomycin hydrochloride monohydrate /kg body weight (b.w.) daily equivalent to 0.2 ml Lincobel / kg b.w. per day.

*Cat:* 20.0 mg lincomycin hydrochloride monohydrate /kg body weight (b.w.) daily equivalent to 0.2 ml Lincobel / kg b.w. per day.

Lincobel must be injected intramuscularly in *pigs* and deep intramuscularly in *dogs* and *cats*.

The duration of treatment is at least three days. The dosage interval is 24 hours.

Should there be no significant improvement 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:

Do not use concomitantly with anaesthetics or active ingredients causing neuro-muscular blockage.

#### Special precautions for use:

##### *Special precautions for use in animals:*

The application of lincomycin should be done under consideration of an antibiogram.

Especially in *pig* herds the resistance situation of the causative germ and different treatment possibilities must be considered in herd problems such as *swine* dysentery or pneumonia.

In the farms affected, it must be strived for avoidance of the repetitive use of Lincobel as a matter of routine by optimising the herd's management as well as livestock breeding and sanitary measures. A reorganisation of stock is to be taken into consideration.

*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:

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

## Interaction with other medicinal products and other forms of interaction:

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, kitasamycin, spiramycin and tilmicosin a partial cross-resistance is observed.

Mixing with other pharmaceuticals should be avoided due to possible incompatibilities. In-vitro incompatibilities are known e.g. for mixtures of lincomycin with penicillins and kanamycin.

There is a distinct antagonism between lincomycin and erythromycin. Due to the identical site of action in the bacterial metabolism, simultaneous application of other macrolide antibiotics is not advisable.

## Overdose (symptoms, emergency procedures, antidotes):

Stop therapy immediately and start emergency care according to the symptoms (see adverse reactions). There is no specific antidote known.

## Incompatibilities:

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

## **Special storage precautions:**

Store at temperatures not 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.

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:** 15802.00.00 (Germany)

**For animal treatment only!**

**Available on prescription only!**