Lincobel

113.4 mg/ml solution for injection

for pigs, dogs and cats

Composition

1 ml solution for injection contains:

Active ingredient:

Lincomycin hydrochloride monohydrate (equivalent to 100.0 mg lincomycin)	113.40 mg

Other ingredients:

Benzyl alcohol	9.45 mg
Water for injection purposes	

Clear, colourless to very slightly brownish solution for injection

Prescription only

MAH-No.: 15802.00.00

Target species(s)

Pig, dog, cat

Indications for use

For the treatment of infectious diseases in pigs caused by lincomycin-susceptible pathogens:

- Aacute and chronic infections in the respiratory tract
- Acute and chronic dermatitis and wound infections
- Metritis
- Arthritides
- Mycoplasma infections
- Pig dysentery

For the treatment of infectious diseases in dogs and cats caused by lincomycin-susceptible pathogens:

- Acute and chronic dermatitis and wound infections
- Metritis
- Mycoplasma infections

Contraindications

Do not use

- in case of resistance and hypersensitivity to lincomycin.
- if liver dysfunction is present.
- in newborns due to possible toxic effects.
- Use in horses, rabbits, hamsters, guinea pigs, chinchillas and ruminating animals (risk of occurrence of severe colitis).

Special warnings

Special warnings:

Do not use at the same time as anaesthetics or agents with a neuromuscular blocking effect.

Special precautions for safe use in the target species:

If renal function is impaired, the dose should be reduced or the dose interval extended.
The use of lincomycin should be based on an antibiogram.

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 the routine repeated use of Lincobel by optimising farm management, e.g. in animal husbandry and hygiene measures. A herd reorganisation should be considered.

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.

Pregnancy and lactation:
Particular care should be taken when using the veterinary medicinal product in lactating animals, as gastrointestinal side effects of lincomycin may occur in very young animals (suckling).
In lactating animals, elimination also takes place via the milk.

Interaction with other medicinal products and other interactions:
Lincomycin enhances the curare-like effects of these muscle relaxants when used concomitantly with anaesthetics or agents with a neuromuscular blocking effect.
There is complete cross-resistance between lincosamides (lincomycin and clindamycin) and partial cross-resistance to markrolide antibiotics such as erythromycin, kitasamycin, spiramycin and tilmicosin.
Mixtures should be avoided due to incompatibilities with other veterinary medicinal products, e.g. lincomycin is incompatible with penicillins and kanamycin in vitro.
There is a clear antagonism between lincomycin and erythromycin. Due to the identical point of attack in bacterial metabolism, simultaneous use with other macrolide antibiotics is not advisable.

Overdosing:
Immediate discontinuation of therapy and emergency measures (see under „Side effects") according to the symptoms. No specific antidote is known.
Major incompatibilities:
As no compatibility studies have been carried out, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events
Pig, dog, cat:

Uncommon (1 to 10 animals / 1,000 animals treated):	Diarrhoea [1] vomiting [1] anorexia [1]
Rare (1 to 10 animals / 10,000 animals treated):	Reddening of the skin [2], agitation, allergic reaction (e.g. anaphylaxis [3], allergic skin reaction [4])
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neuromuscular blockade [5] Agranulocytosis, leucopenia, thrombocytopenia, increase in aspartate aminotransferase, cardiac dysfunction [7] , hypotension
Undetermined frequency (cannot be estimated based on available data)	Swelling of the vulva [2] , anal oedema [2] Irritation at the injection site [6]

[1] If gastrointestinal disorders occur shortly after starting treatment or if existing diarrhoea worsens, therapy should be discontinued or changed.
[2] In pigs, occurring within 18 to 36 hours after the start of treatment, in the anal and vulva area, subsiding on its own over the course of five to seven days of treatment
[3] Countermeasure: Adrenalin (epinephrine) and glucocorticoids i.v.
[4] Countermeasure: antihistamines and/or glucocorticoids
[5] Can only be partially cancelled by calcium. Indirectly acting parasympathomimetics (e.g. neostigmine) are not effective.
[6] low grade
[7] Influencing the conduction velocity in the heart

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details, or via your national reporting system. Notification forms and contact details of the BVL can be found on the website https://www.vet-uaw.de or can be requested by e-mail (uaw@bvl.bund.de). Veterinarians have the option of electronic reporting on the above-mentioned website.

Dosage for each animal species, type and duration of use
Intramuscular application
Pig: 10 mg i.m. / kg bw / day = 0.1 ml of the veterinary medicinal product / kg bw
Dog: 20 mg i.m. / kg bw / day = 0.2 ml of the veterinary medicinal product / kg bw
Cat: 20 mg i.m. / kg bw / day = 0.2 ml of the veterinary medicinal product / kg bw

The veterinary medicinal product should be administered intramuscularly in pigs and deeply intramuscularly in dogs and cats.
The duration of treatment should be at least three days (dosing interval 24 hours).
If there is no significant improvement in the patient's condition after three days of treatment, the diagnosis should be reviewed and the therapy changed if necessary.

Advice on correct administration
See section „Dosage for each target species, route and duration of administration".

Withdrawal periods
Pigs: Edible tissues: 7 days

Special storage precautions
Keep medicine out of the reach of children. Do not store above 25 °C after opening.
Shelf life after first opening/opening of the primary packaging: 7 days.
Any remaining quantities of the medicinal product in the container must be discarded after the expiry date after opening.
Do not use this veterinary medicinal product after the expiry date stated on the label after „Exp". The expiry date refers to the last day of the month.

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. These measures serve to protect the environment. Ask your vet or pharmacist how to dispose of medicines that are no longer needed.

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

Marketing authorisation numbers and pack sizes
15802.00.00

Clear 100 ml glass type II vial with bromobutyl rubber stopper and aluminium crimp cap.
Pack sizes Original packaging:
(1 x 100 ml)
(5 x 100 ml)
(6 x 100 ml)
(10 x 100 ml)
(12 x 100 ml)

Pack sizes Bundle packs:
5 x (1 x 100 ml)
6 x (1 x 100 ml)
10 x (1 x 100 ml)
12 x (1 x 100 ml)
8 x (6 x 100 ml)
4 x (12 x 100 ml)
Not all pack sizes may be placed on the market.

Date on which the package leaflet was last revised
11.12.2024

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