SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincoject 10 % w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Lincomycin 10.0% w/v [100 mg/ml]
(as Lincomycin hydrochloride 11.34% w/v [113.4 mg/ml])

Excipients:
Benzyl Alcohol 0.9% w/v [9mg/ml]

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection
A clear, colourless solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Pigs
Dogs
Cats

4.2 Indications for use, specifying the target species

In dogs and cats, Lincoject is recommended for the treatment of infections caused by Lincomycin susceptible Gram-positive organisms, particularly streptococci and staphylococci and certain Gram-negative anaerobic bacteria (e.g. Bacteroides, Fusobacterium species).

Lincoject is recommended for treatment of the following conditions in dogs and cats: Tonsillitis, laryngitis and other respiratory tract infections; abscesses, infected wounds and purulent dermatitis; septicaemia.

In pigs, Lincoject is indicated for the treatment of infections caused by Lincomycin susceptible Gram-positive organisms (e.g. staphylococci, streptococci), certain Gram-negative anaerobic organisms (e.g. *Serpulina (Treponema) hyodysenteriae*, Bacteroids, Fusobacterium and Mycoplasma species).

Lincoject is recommended for treatment of the following conditions in pigs: Swine dysentry, enzootic or mycoplasmal pneumonia, septic arthritis, foot abscesses.

4.3 Contraindications

The use of Lincoject is not recommended in species other than the cat, dog and pig. Lincosamides may cause fatal enterocolitis in horses, rabbits and rodents and diarrhoea and reduced milk production in cattle.

Lincoject should not be given to animals with a known pre-existing monilial infection.

Not to be used in animals hypersensitive to Lincomycin

4.4 Special Warnings for each target species

When treating groups of pigs, the use of a multiple dose syringe is recommended. To refill the syringe, the use of a draw-off needle is recommended to avoid excessive broaching of the stopper.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dosage.
Practice aseptic injection techniques.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

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

Avoid contact with the product. In case of accidental eye or skin contact, wash off the affected area thoroughly with water.

4.6 Adverse reactions (frequency and seriousness)

The intramuscular administration of Lincoject to pigs at higher levels than recommended may result in diarrhoea and loose stools.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

Not compatible with penicillin and erythromycin if used concurrently.

4.9 Amounts to be administered and administration route

Lincoject is indicated for intravenous and intramuscular administration to dogs and cats and intramuscular administration to pigs.

CATS AND DOGS:
Intramuscularly: 22 mg/kg of bodyweight once daily or 11 mg/kg every 12 hours.

Intravenously: 11 to 22 mg/kg one or two times per day by slow intravenous injection.

PIGS:
Intramuscularly: 4.5 to 11 mg/kg of bodyweight once daily.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The intramuscular administration of Lincoject to pigs at higher levels than recommended may result in diarrhoea and loose stools.

4.11 Withdrawal period

Animals must not be slaughtered for human consumption during treatment.

Pigs (Meat): 3 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATC Vet Code: QJ01FF02

5.1 Pharmacodynamic properties

The mode of action is inhibition of protein synthesis at the ribosomal 50S subunit level. Lincomycin is primarily excreted in the faeces as both parent compound and metabolites with large biliary contribution. After administration of the recommended single dosage, faecal excretion accounts for 38% and urinary excretion for 49% of the total dose. The antibiotic is transported in polymorphonuclear leucocytes to the site of infection, an event that may explain the efficient penetration and targeting of organisms in tissues difficult to reach by diffusion in the presence of purulent material.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Water for Injections

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 Years.

Shelf life after first opening the immediate packaging: 28 Days.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.
Following withdrawal of the first dose use the product within 28 days. Discard unused product.

6.5 Nature and composition of immediate packaging

100 ml Type I clear colourless glass vials, complete with bromobutyl bungs and aluminium caps.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry, Co. Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

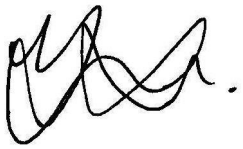
02000/4183

9. DATE OF FIRST AUTHORISATION

20 November 2001

10. DATE OF REVISION OF THE TEXT

April 2022



Approved: 27 April 2022