SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LINCOCIN STERILE SOLUTION 100 mg/ml Sterile Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains 100 mg lincomycin (as lincomycin hydrochloride) plus 9 mg benzyl alcohol as antimicrobial preservative.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats and pigs.

4.2 Indications for use, specifying the target species

Dogs and cats
For the treatment of infections caused by lincomycin-susceptible Gram-positive organisms, particularly Streptococci and Staphylococci, and certain Gram-negative anaerobic organisms e.g. Bacteroides spp. or Fusobacterium spp.
Tonsillitis, laryngitis and other upper respiratory tract infections: The product has proved effective against most causal organisms.
Abscesses, infected wounds and purulent dermatitis: The product has proved useful in clearing dermal infection since it readily penetrates tissues and maintains its action in the presence of purulent material.
Septicaemia: The product has been used successfully to combat septicaemic conditions caused by organisms sensitive to lincomycin.

Pigs
For the treatment of infections caused by lincomycin-susceptible Gram-positive organisms, particularly Streptococci and Staphylococci, and certain Gram-negative anaerobic organisms e.g. *Serpulina (treponema) hyodysenteriae*, Bacteroides, Fusobacterium spp. and Mycoplasma spp.
Swine dysentery: Lincocin Sterile Solution has been found effective in the treatment of swine dysentery. Lincocin Sterile Solution may be used in the inappetent pig when 1-2 injections with a 24 hour interval given intramuscularly at a dose of 10 mg/kg will normally be adequate to return the appetite. Follow-up treatment should be provided either in feed or via the drinking water.
Enzootic or mycoplasmal pneumonia: the product has antimycoplasmal activity, and will provide an effective aid in the treatment of primary infective organisms and the secondary Gram-positive pathogens.

Septic arthritis, foot abscesses: Where these conditions are caused by staphylococci, streptococci, erysipelothrix and mycoplasma sensitive to lincomycin, this antibiotic provides useful treatment by the virtue of its ability to penetrate relatively avascular tissue (e.g. joints) and remain active in the presence of purulent material.

4.3 Contraindications

Not recommended for use in species other than the dog, cat and pig. Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants as this could result in severe gastro-intestinal disturbance.
Not to be given to animals with known pre-existing monilial infection.
Not effective against *E.coli*, *Salmonella spp*., *Streptococcus faecalis* or yeasts.
Not to be used in animals hypersensitive to lincosamides.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Not applicable.

ii) 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)

Not applicable.

4.7 Use during pregnancy, lactation or lay

Limited studies in experimental animals did not reveal any problems when lincomycin was used during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Clinical antagonism may exist between lincomycin and erythromycin and concurrent use is therefore not recommended.

4.9 Amounts to be administered and administration route

For intramuscular or intravenous administration in dogs and cats. For intramuscular administration only in pigs.

Dogs and cats:
Intramuscular: 22 mg/kg bwt once daily or 11 mg/kg bwt.
Intravenous: 11-22 mg/kg bwt once or twice daily by slow injection.

Pigs:
Intramuscular: 4.5-11 mg/kg bwt once daily for a maximum of 3 days.
When injecting large volumes, a maximum of 10 mls per injection site should be administered. It is recommended that no more than two injections per day are given. At the lowest dose rate of 4.5 mg/kg, the maximum recommended weight of animal for treatment is therefore 445 kg and at the higher dose rate of 11 mg/kg, the maximum weight of animal for treatment will be 180 kg.

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

Higher levels of dosage than recommended may cause diarrhoea and loose stools in pigs.

4.11 Withdrawal periods

Animals must not be slaughtered for human consumption during treatment.
Pigs may be slaughtered for human consumption only after 3 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Lincomycin is a lincosamide antibiotic and is produced by S*treptomyces lincolnensis*. It is bacteriostatic and primarily active against Gram-positive bacteria (both aerobic and anaerobic), Gram-negative anaerobic bacteria and mycoplasma.
The mode of action is inhibition of protein synthesis at the ribosomal 50S sub-unit level. Lincomycin is quickly absorbed and distributed throughout the body, it is significantly metabolised, and is primarily excreted in the faeces as both parent compound and metabolites with large biliary contribution; after a single intramuscular injection at the recommended dose faecal excretion accounted for 38% and urinary excretion for 49% of the total dose. Lincomycin is transported by polymorphonuclear neutrophils to the infection area; this may explain its efficient penetration and targeted activity in tissues difficult to reach.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol

Sodium hydroxide
Hydrochloric acid
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 21 days.

6.4 Special precautions for storage

Do not store above 25ºC. Do not freeze.
Discard contents within 21 days after first use.

6.5 Nature and composition of immediate packaging

Multidose 50 ml and 100 ml glass vials with rubber stopper and aluminium overseal.
Not all pack sizes may be marketed.

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

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5200

9. DATE OF FIRST AUTHORISATION

20 July 1992

10. DATE OF REVISION OF THE TEXT

May 2025

Gavin Hall
Approved: 22 May 2025