1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincocin 100 mg/ml Sterile Solution for injection for dogs, cats and pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Lincomycin 100 mg (as Lincomycin hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	9 mg
Water for injection	

Clear colourless aqueous sterile solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats and pigs.

3.2 Indications for use for each target species

Dogs and cats: For the treatment of infections caused by lincomycin susceptible Gram-positive organisms, particularly streptococci and staphylococci and certain anaerobic bacteria e.g. *Bacteroides, Fusobacterium* spp.

Pigs: 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, Bacteroides*, *Fusobacterium* spp., and *Mycoplasma* spp..

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or the excipient.
Do not use in animals with known pre-existing monilial infection.
Concurrent treatment with erythromycin is not recommended.
Do not use in species other than dogs, cats or pigs.
Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants as this could result in severe gastro-intestinal disturbance.

3.4 Special warnings

Do not use against *E. Coli*, *Salmonella* spp., *Enterococcus faecalis* or yeasts.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs, cats and pigs:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Clinical incompatibility may exist between lincomycin and erythromycin due to competitive binding at the ribosomal site of action.

3.9 Administration routes and dosage

Dogs and Cats:
Intramuscular use or intravenous use.

If the intravenous route is used in dogs and cats, the injection should be made slowly.
The recommended dosage rate for dogs and cats is 22 mg/kg bodyweight (equivalent to 1 ml per 4.5kg bodyweight) once daily or 11 mg/kg bodyweight (equivalent to 1 ml per 9 kg bodyweight) every 12 hours.

Pigs:
Intramuscular use.

The recommended dosage rate for pigs is 4.5-11 mg/kg bodyweight once daily (equivalent to 1 ml per 9 to 22 kg bodyweight depending on dosage rate selected).

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The administration of the veterinary medicinal product to pigs at higher levels than recommended may result in diarrhoea and loose stools.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Pigs:
Meat and offal: 48 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01FF02

4.2 Pharmacodynamics

Lincomycin is a lincosamide antibiotic and is produced by *Streptomyces 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25°C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Cardboard box with 100 ml multi-dose glass (Type I) vials with rubber stoppers and aluminium overseal.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10387/039/001

8. DATE OF FIRST AUTHORISATION

10/10/2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

12/12/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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