1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Spectin Sterile Solution for injection for pigs, non-ruminating calves, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Lincomycin (as lincomycin hydrochloride)	50 mg
Spectinomycin (as spectinomycin sulphate)	100 mg

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
Sodium hydroxide	
Hydrochloric acid	
Water for injections	

A colourless to light yellow sterile solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs, non-ruminating calves, dogs and cats.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of infections caused by organisms sensitive to the action of lincomycin and / or spectinomycin including:

Actinobacillus spp.
Pasteurella spp.
Serpulina hyodysenteriae
Escherichia coli
Salmonella spp.
Campylobacter spp.
Bacteroides spp.
Clostridium spp.
Fusobacterium spp.
Actinomyces spp.
Streptococcus spp.
Mycoplasma spp.

3.3 Contraindications

Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants as this could result in severe gastro-intestinal disturbance.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

None.

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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs, non-ruminating calves, dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea[1], Loose stool[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain Appetite loss

[1] In pigs only. Transient.

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

None known.

3.9 Administration routes and dosage

Intramuscular use.

Pigs: 15 mg combined activity per kg bwt (1 ml/10 kg bwt) intramuscularly, to be repeated daily for 3 days according to clinical response.

Non-ruminating calves: 15 mg combined activity per kg bwt (1 ml/10 kg bwt) intramuscularly twice daily for the first day followed by once daily for 2-4 days according to clinical response.

Dogs and cats: 30 mg combined activity per kg bwt (1 ml/5 kg bwt) intramuscularly. May be repeated at 12 to 24 hour intervals for 3-7 days according to clinical response

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

Not applicable.

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: 14 days.

Non-ruminating calves:
Meat and offal: 21 days.

Do not use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01FF52

4.2 Pharmacodynamics

The product contains both lincomycin and spectinomycin. Lincomycin is a lincosamide antibiotic with activity against a wide range of Gram-positive and Gram-negative bacteria and mycoplasma. It is well distributed throughout the body and is significantly metabolised. Spectinomycin is an aminocyclitol antibiotic and is also active against mycoplasma as well as many Gram-negative bacteria, particularly members of the Enterobacteriaceae. It is also well distributed throughout the body and appears to be mainly excreted as the parent compound.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not dilute or mix with other compounds.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Cardboard box with 100 ml multi-dose colourless Type 1 (Ph.Eur) glass vials with butyl rubber stopper 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)

VPA10387/041/001

8. DATE OF FIRST AUTHORISATION

09/12/2013

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

24/01/2025

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*).