## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LINCOVEX 100 mg/ml solution for injection for pigs, cats and dogs.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**
Lincomycin (as lincomycin hydrochloride monohydrate)……100.0 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 (E 1519) | 9.0 mg |
| Water for injections | |

A clear, colorless 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 Gram-positive organisms, particularly streptococci and some anaerobic bacteria.

Pigs: for the treatment of infections caused by Gram-positive bacteria, some anaerobic bacteria and mycoplasma.

### 3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with known pre-existing monilial infection.
Concurrent treatment with erythromycin is no recommended.
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 liver dysfunction.

### 3.4 Special warnings

Do not use against *E. Coli*, Salmonella spp., *Enterococcus faecalis* or yeasts.
Cross-resistance has been shown between lincomycin and others lincosamides, macrolides and streptogramin B antibiotics. Use of the product should be carefully considered when susceptibility testing has shown resistance to lincosamides, macrolides and streptogramin B antibiotics because its effectiveness may be reduced.
In some European regions, a high proportion of *Brachyspira hyodysenteriae* isolates resistant to lincosamides have been detected from clinical cases in pigs.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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

This veterinary medicinal product contains lincomycin and benzyl alcohol, which may cause allergic reactions in some individuals. People with known hypersensitivity to lincomycin or any other lincosamide, or to benzyl alcohol should avoid contact with the veterinary medicinal product.

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

Immediately after use, wash hands with soap and water.

Do not eat, drink or smoke when handling the product.

Take care when administering the product to avoid accidental self-injection. In case of accidental self-injection seek medical attention immediately and show the package leaflet or the label to the physician.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Dogs, cats and pigs:

| | |
|---|---|
| Undetermined frequency (cannot be estimated from the available data): | Loose stool[1]<br>Injection site reactions NOS |

[1] Especially in animals treated with high doses.

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 its local representative 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

Laboratory studies in rats have not produced any evidence of teratogenic effects, although foetotoxicity has been reported. The safety of the veterinary medicinal product during pregnancy or lactation in the target species has not been established.

Pregnancy
Use only according to the benefit-risk assessment by the responsible veterinarian.

### 3.8 Interaction with other medicinal products and other forms of interaction

Clinical interaction may exist between lincomycin and erythromycin when both are administered concomitantly due to competitive binding at the ribosomal site of action.

Lincomycin possesses intrinsic neuromuscular blocking activity and should be used cautiously with other neuromuscular blocking agents.

*In vitro* antagonism is noted when lincomycin is used concomitantly with bactericidal antibiotics active on growing bacteria.

### 3.9 Administration routes and dosage

Dogs and cats: intramuscular or slow intravenous use.
Pigs: intramuscular use.

Dogs and cats:
The recommended dosage rate for dogs and cats is 22 mg lincomycin/kg bodyweight (equivalent to 1 ml of veterinary medicinal product per 4.5 kg bodyweight) once daily or 11 mg lincomycin/kg bodyweight (equivalent to 1 ml of veterinary medicinal product per 9 kg bodyweight) every 12 hours.

Pigs:
The recommended dosage rate for pigs is 11 mg lincomycin/kg bodyweight once daily (equivalent to 1 ml of veterinary medicinal product per 9 kg bodyweight) for 3 consecutive days.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Do not puncture the stopper more than 30 times with 22 G syringe or 15 times with 18 G syringe. Otherwise, automatic syringe equipment, or a suitable draw-off needle, should be used to avoid excessive puncturing of the closure.

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

Higher levels of dosage than recommended may cause transient soft stools or diarrhoea in pigs.

There is no specific antidote, treatment is symptomatic.

### 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: 3 days.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code:

QJ01FF02.

### 4.2 Pharmacodynamics

Lincomycin is a lincosamide antibiotic and is produced by *Streptomyces lincolnensis*. It exerts its bacteriostatic action by inhibiting RNA-dependent protein synthesis by acting on the 50S subunit of the ribosome.
It is primarily active against Gram-positive bacteria (both aerobic and anaerobic), Gram-negative anaerobic bacteria and mycoplasma.Mechanisms of resistance to lincomycin include efflux of the antibiotic and drug inactivation, and the most widespread mechanism which is target-site modification by methylation or mutation that prevents the binding of the antimicrobial to its ribosomal target. The rRNA methylases are encoded by different erythromycin-resistant methylase (erm) genes that can be horizontally transferred. This mechanism of target site modification can confer cross-resistance to macrolides, other lincosamides, and streptogramins B (i.e., MLSB phenotype)
Furthermore, resistance genes can be located on plasmids or transposons, such as the *vga* genes and the *cfr* gene (conferring cross-resistance between pleuromutilins, oxazolidinones, phenicols, streptogramin A, and lincosamides). This type of resistance is transferable between bacteria and bacterial species. The mechanism of antimicrobial resistance varies among bacterial species.

### 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

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### 5.2 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.

### 5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

### 5.4 Nature and composition of immediate packaging

Translucent polypropylene vial closed with a type I bromobutyl rubber stopper and aluminium cap with Flip-Off® sealing.

Pack sizes:
Carton box with 1 vial of 100 ml
Carton box with 1 vial of 250 ml

Not all pack sizes may be marketed.

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

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

The veterinary medicinal product should not enter water courses as lincomycin may be dangerous for aquatic organisms.

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

SP Veterinaria, S.A.,

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10790/015/001

## 8. DATE OF FIRST AUTHORISATION

20/12/2023

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

## 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*).