## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincocin Sterile Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance
Lincomycin 100 mg
(as Lincomycin Hydrochloride)

Excipients
Benzyl alcohol 9 mg For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for injection.
Clear colourless aqueous sterile solution.

## 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 Gram-positive organisms which are sensitive to linocomycin, particularly streptococci and some anaerobic bacteria.

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

### 4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in animals with known pre-existing monilial infection.
Concurrent treatment with erythromycin is not recommended.
Not for use in species other than dog, cat or pig. Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants as this could result in severe gastro-intestinal disturbance.

**4.4 Special warnings for each target species**

If the intravenous route is used in dogs and cats, the injection should be made slowly. Do not use against *E. Coli*, Salmonella spp., *Enterococcus faecalis* or yeasts.

**4.5 Special precautions for use**

**Special precaution(s) for use in animals**
None.
**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**

No restrictions.

**4.8 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.

**4.9 Amounts to be administered and administration route**

Dogs and Cats:
For intramuscular or slow intravenous use in dogs and cats
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:
For intramuscular use only in pigs
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).

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

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

### 4.11 Withdrawal period(s)

Pigs:
Meat and offal: 48 hours.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Lincosamides
ATCvet Code: QJ01FF02

### 5.1 Pharmacodynamic properties

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.

### 5.2 Pharmacokinetic properties

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
Water for Injection

### 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: 28 days.

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

Presented in 100 ml multi-dose glass (Type I) vials with rubber stoppers and aluminium overseal packed in outer cardboard box.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

## 7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/039/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation 1st October 1988
Date of last renewal: 16th October 2009

## 10 DATE OF REVISION OF THE TEXT

July 2017