Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Linspec 50/100 mg/ml Solution for injection for dogs, cats, pigs and pre-ruminant calves

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Lincomycin (as lincomycin hydrochloride)	50	mg
Spectinomycin (as spectinomycin sulfate tetrahydrate)	100	mg

Excipients

Benzyl alcohol (E1519)	9	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (pre-ruminating calves), Pigs, dogs and cats.

4.2 Indications for use, specifying the target species

Treatment of respiratory infections, intestinal infections, urinary tract infections, skin infections (including wounds and abscess) and arthritis caused by organisms sensitive to lincomycin and / or spectinomycin including:
Actinobacillus spp.
Pasteurella spp.
Brachyspira hyodysenteriae
Escherichia coli
Salmonella spp.
Campylobacter spp.
Bacteroides spp.
Clostridium spp.
Fusobacterium spp.
Actinomyces spp.
Staphylococcus spp.
Streptococcus spp.
Mycoplasma spp.

4.3 Contraindications

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

None.

4.5 Special precautions for use

Special precautions for use in animals.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the veterinary medicinal product deviating from the instructions in the SPC may increase the risk of development and selection of resistant bacteria and decrease the effectiveness of treatment with macrolides due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Lincomycin and spectinomycin can cause hypersensitivity (allergy) after injection, inhalation, ingestion or spillage onto skin. Allergic reactions to these substances can be severe.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Avoid contact with skin and eyes. Wash any splashes off immediately with plenty of water. Wash hands after use. People with known hypersensitivity to lincomycin and spectinomycin should avoid contact with the veterinary medicinal product.
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.

4.6 Adverse reactions (frequency and seriousness)

The use of this product may cause occasional local discomfort upon injection. Transient diarrhoea or loose stools may occur rarely. An occasional loss of appetite may also occur.

4.7 Use during pregnancy, lactation or lay

The safety of the product has not been assessed during pregnancy and lactation and in breeders. Use only after according to the risk-benefit assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer with macrolides.
Combination with anaesthetics may lead to possible neuromuscular blocking.

4.9 Amounts to be administered and administration route

By intramuscular injection.
To ensure a correct dosage body weight should be determined as accurately as possible.

Pigs:
5 mg of lincomycin and 10 mg spectinomycin per kg bodyweight (corresponding to 1 ml of the product /10 kg bw) intramuscularly, to be repeated daily for 3 days according to clinical response.

Pre-ruminating calves:
5 mg of lincomycin and 10 mg spectinomycin per kg bodyweight (corresponding to 1ml of the product /10kg bw) intramuscularly twice daily for the first day followed by once daily for 2-4 days according to clinical response.

Dogs and cats:
10 mg of lincomycin and 20 mg spectinomycin per kg bw (corresponding to 1 ml of the product per 5 kg bw) intramuscularly. May be repeated at 12 to 24 hour intervals for 3-7 days according to clinical response.

A vial cannot be broached more than 30 times, the user should choose the most appropriate vial size for the target species.

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

Do not exceed the recommended dose. At higher levels than recommended in pigs, the product may give rise to transient diarrhoea or loose stools.

4.11 Withdrawal Period(s)

Meat and offal
Pigs: 14 days.
Cattle (Pre-ruminating calves): 21 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Lincomycin, combinations
ATCvet code: QJ01FF52

5.1 Pharmacodynamic properties

Lincomycin is a lincosamide antibiotic with activity against a wide range of Gram-positive and Gram-negative bacteria and mycoplasma.
Spectinomycin is an aminocyclitol antibiotic and is also active against mycoplasma as well as many Gram-negative bacteria, particularly members of the Enterobacteriaceae.
The multiplicity of mechanisms of resistance to antibiotics includes ribosomal modification, efflux of the antibiotic, and drug inactivation, which results in a variety of phenotypes of resistance. The most common mechanism of resistance to lincosamides involves N^6 dimethylation of a specific adenine residue (A2058) of the 23S rRNA molecule. This alteration of the antibiotic target site is invariably catalyzed by an rRNA methyltransferase encoded by *erm* genes.
The amynoglycosides inactivation mechanism is of most clinical importance since the genes encoding aminoglycoside modifying enzymes can be disseminated by plasmids or transposons.
Cross-resistance has been suggested between lincomycin and clindamycin since they belong at the same antimicrobial class. In Europe, strains of *Staphylococcus aureus* and of *Streptococcus uberis* resistant against lincomycin and strains of *Salmonella enterica* and *Escherichia coli* resistant against spectinomycin have been isolated.

5.2 Pharmacokinetic properties

Lincomycin is well distributed throughout the body and is significantly metabolised.
Spectinomycin is also well distributed throughout the body and appears to be mainly excreted as the parent compound.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium hydroxide
Hydrochloric acid
Water for injections

6.2 Incompatibilities

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

6.3 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.

6.4 Special precautions for storage

Do not store above 25 ºC.

6.5 Nature and composition of immediate packaging

100 ml and 250 ml multi-dose translucent polypropylene vials with bromobutyl stopper and aluminium cap with a flip-off seal. These vials are placed in an outer container (paper box).
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/079/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th July 2010
Renewal of the last authorisation: 28th July 2015

10 DATE OF REVISION OF THE TEXT