Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Spectin Premix for medicated feed.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg contains:		
Lincomycin (as lincomycin hydrochloride)	22	g
Spectinomycin (as spectinomycin sulphate)	22	g
Excipients		
Liquid Paraffin	10	g
Soyabean mill feed carrier qs ad.	1	kg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Premix for medicated feed.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

For the control and treatment of swine dysentery caused by *Serpulina hyodysenteriae* associated with *Fusobacterium, Bacteroides, Clostridium* and/or *Campylobacter* spp. sensitive to the combination lincomycin and spectinomycin.

For the control and treatment of entertitis in pigs caused by *Escherischia coli* and *Salmonella* spp. sensitive to the combination lincomycin and spectinomycin. The product has been shown to be particularly effective against complicated or mixed enteric infections involving the above organisms.

For the control and treatment of enteritis associated with *Lawsonia intracellularis* (ileitis) in pigs.

As an aid in the control of mycoplasmal (enzootic) pneumonia in pigs.

For the treatment of Mastitis, Metritis, Agalactiae (MMA) syndrome of bacterial origin sensitive to the combination in sows.

Linco-Spectin is active in vitro against:
Serpulina hyodysenteriae
Bacteroides spp.
Fusobacterium spp.
Clostridium spp.
Escherichia coli.
Salmonella spp.
Campylobacter spp.
Staphylococcus spp.
Streptococcus spp.
Mycoplasma spp.

4.3 Contraindications

Do not use in animals previously shown to be hypersensitive to the active substances.
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

Loosening of faeces and/or mild swelling of the anus may occur; this is usually transient. On rare occasions, mild irritability and reddening of skin may occur. These conditions are usually self-correcting within five to eight days without discontinuing therapy.
If clinical signs are not improved during the first 10 days of medication, discontinue treatment and redetermine the diagnosis.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Care should be taken not to inhale any dust. Skin contact should be avoided. Hands and exposed skin should be washed after handling the product or medicated feed.

4.6 Adverse reactions (frequency and seriousness)

Loosening of faeces and/or mild swelling of the anus may occur; this is usually transient. On rare occasions, mild irritability and reddening of skin may occur. These conditions are usually self-correcting within five to eight days without discontinuing therapy.

4.7 Use during pregnancy, lactation or lay

May be used during pregnancy and lactation. Do not use in animals producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

No negative interactions known. The product has been shown to be clinically compatible with salinomycin.

4.9 Amounts to be administered and administration route

Enteric disease:
Treatment: 2 kg product/tonne feed for 3 weeks or until clinical signs disappear.
Control: 1 - 2 kg product/tonne feed over period of risk.

Aid in the control of mycoplasmal pneumonia: 1 - 2 kg product/tonne feed over period of risk.

Treatment of MMA: 1 - 2 kg product/tonne feed for 5 - 10 days prior to farrowing and 2 - 3 weeks post-farrowing.

To ensure thorough dispersion of the product it should be first mixed with a suitable quantity of feed before incorporation into the final mix. The product can be incorporated into pelleted feed at a processing temperature not exceeding 70°C.

When incorporated at a rate of below 2 kg per tonne of final feed, the product must only be mixed by a manufacturer who is approved to mix at that level.

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

Not applicable.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered during treatment. Animals intended for human consumption may only be slaughtered from 24 hours after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

The product contains the antibiotics lincomycin and spectinomycin. Lincomycin is a lincosamide antibiotic and is produced by *Streptomyces lincolnensis.* It is bacteriostatic and is primarily active against Gram-positive bacteria (both aerobic and anaerobic), Gram-negative anaerobic bacteria and mycoplasmas.

The mode of action is inhibition of protein synthesis at the ribosomal 50S sub-unit level. Lincomycin has about 50% systemic boiavailability by the oral route in pigs. It is primarily excreted in the faeces as both parent compound and metabolites with large biliary contribution. Spectinomycin is an aminocyclitol antibiotic and is produced by *Streptomyces spectabilis.* It is bacteriostatic and is primarily active against Gram-negative bacteria.

Its mode of action is inhibition of protein synthesis at the ribosomal 30S sub-unit level. Spectinomycin is not well absorbed by the oral route and the vast majority (>90%) is retained in the gut and excreted in the faeces.

Lincomycin and spectinomycin have been shown to be synergistic *in vitro* against anaerobes implicated in the pathogenesis of swine dysentery.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Soyabean mill feed carrier

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months

Shelf life after incorporation into feed: 3 months

6.4 Special precautions for storage

Do not store above 25^{o}C. Store opened bag in a dry place to prevent caking.

6.5 Nature and composition of immediate packaging

Fine slightly yellow flakes as a premix contained in 2 kg polyester/aluminium foil/ polyethylene bag and 20 kg and 25 kg multi-walled polyethylene lined paper bags.

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

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/065/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th September 2007

Date of last renewal: 23rd April 2010

10 DATE OF REVISION OF THE TEXT

January 2015