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 22g lincomycin (as lincomycin hydrochloride) and 22g spectinomycin (as spectinomycin sulphate) together with 10 g mineral oil in soyabean mill feed carrier (qs ad. 1kg).

For the full list of all other excipients see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

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 enteritis in pigs caused by *Escherichia 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 of lincomycin and spectinomycin in sows.

4.3 Contraindications

Do not allow horses, ruminating animals, guinea pigs, hamsters or rabbits access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

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

(i) Special precautions for use in animals

When an antibiotic treatment programme is prescribed, consideration should be given to ensuring good management practices are also in place.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Persons known to be hypersensitive (allergic) to lincomycin, spectinomycin or soybean millfeed should not handle this product.

Care should be taken not to inhale any dust. The wearing of approved dust masks (either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143) and safety glasses is recommended during the handling and mixing of this product.

Skin contact should be avoided.

Wash hands and any exposed skin with soap and water immediately after use.

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

No restriction.

4.8 Interaction with other medicinal products and other forms of interaction

No negative interactions known. Linco-Spectin has been shown to be clinically compatible with salinomycin.

4.9 Amounts to be administered and administration route

For incorporation into dry feed at the registered mill.

For oral administration only.

Treatment and control of 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.

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

Aid in the control of mycoplasmal pneumonia: 1-2 kg product per tonne of feed and feed daily throughout the period of risk.

To ensure thorough dispersion of the product it should first be 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 2kg 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

See sections 4.6 (Adverse reactions) and 4.4 (Special warnings for each target species).

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment
Pigs may be slaughtered for human consumption only after 2 days from last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Antibacterials for systemic use, Combinations of antibacterials

ATC Vet Code: QJ01RA94

Linco-Spectin Premix 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 bioavailability

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
Soybean Millfeed

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 meal or pelleted food: 3 months.

6.4. Special precautions for storage

Do not store above 25˚C.
Store in a dry place.
Store opened bag in a dry place to prevent caking.
The product will remain stable in the finished feed and in pelleted feed for 3 months.

6.5 Nature and composition of immediate packaging

Polyethylene lined aluminium/polyester laminated sachets of 2kg. Multi-walled polyethylene-lined bags of 20kg.

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

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4081

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd December 1994

10. DATE OF REVISION OF THE TEXT

August 2013

Approved: 07/08/2013