SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LINCOCIN™ PREMIX
44 g/kg Premix for Medicated Feed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kilogram contains lincomycin (as lincomycin hydrochloride) 44 g plus 10g mineral oil q.s ad 1 kg soyabean millfeed carrier.

For the full list of all other 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 and mycoplasmal pneumonia.

4.3 Contraindications

Do not administer to animals with known hypersensitivity to the active ingredient.
Not for use in animals other than the target species. Lincomycin may cause fatal enterocolitis in horses, rodents and rabbits.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

Not applicable.

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

Persons known to be hypersensitive (allergic) to lincomycin and/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)

May occasionally cause transient soft stools and/or mild swelling of the anus within the first two days of treatment. Very rarely some pigs may show reddening of skin and mild irritable behaviour. These conditions are usually self-correcting within 5-8 days without discontinuing lincomycin treatment.

4.7 Use during pregnancy, lactation or lay

Not applicable.

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

For incorporation into dry feed at the registered mill.

To be administered orally via the feed.

Control of swine dysentery: Feed 44 grams lincomycin per tonne (1000 kg) of complete feed as the sole ration throughout the period of risk.

Treatment of swine dysentery: Feed 110 grams of lincomycin per tonne (1000 kg) of complete feed as the sole ration for three weeks or until clinical signs of disease (watery, mucoid or bloody stools) disappear.

Treatment and control of swine mycoplasmal pneumonia: Feed 220 grams of lincomycin per tonne (1000 kg) of complete feed as the sole ration for three weeks or until clinical signs of disease disappear.

Mixing Directions:

For the control of swine dysentery: to make complete feed containing 44 grams of lincomycin per tonne, add 1 kg of Lincocin Premix per tonne (1000 kg).

For the treatment of swine dysentery: to make complete feed containing 110 grams of lincomycin per tonne, add 2.5 kg of Lincocin Premix per tonne (1000 kg).

For the treatment and control of swine mycoplasmal pneumonia: to make complete feed containing 220 grams of lincomycin per tonne, add 5 kg of Lincocin Premix per tonne (1000 kg).

To ensure thorough dispersion of the product it should first be mixed with a suitable quantity of feed before incorporation into the final mix.

For inclusion rates less than 2 kg/tonne: Category A manufacturers only.

Incorporation into pig feeding stuffs must follow the product licence directions given above or be in accordance with a Medicated Feedingstuffs Prescription.

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

Not applicable.

4.11 Withdrawal periods

Animals must not be slaughtered for human consumption during treatment.

Withdrawal periods for the different dosing regimes are as shown below.

Indication	Dosage	Withdrawal Period
Swine dysentery	44 or 110g lincomycin / tonne feed	24 hours
Swine mycoplasmal pneumonia	220g lincomycin / tonne feed	3 days

5. PHARMACOLOGICAL PROPERTIES

Lincomycin is a lincosamide antibiotic and is active against a wide range of Gram-positive aerobic and anaerobic bacteria, anaerobic Gram-negative bacteria and mycoplasma. Lincosamides are generally bacteriostatic. It is active against the primary causal agent of swine dysentery, *Serpulina hyodysenteriae* and the exacerbating anaerobes, Bacteroides, Fusobacterium and Clostridium spp, and also of mycoplasmal (enzootic) pneumonia in pigs, *Mycoplasma hyopneumoniae*. Lincomycin has approximately 50% systemic bioavailability from oral administration in pigs and is significantly re-circulated via the biliary route.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin
Soybean Mill Feed

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 incorporation into meal or pelleted feed: 3 months.

6.4. Special precautions for storage

Do not store above 25˚C.
Store in a dry place.
Lincomycin remains stable in medicated feed for 3 months.

6.5 Nature and composition of immediate packaging

Polyethylene lined polyester (or paper) bags; heat sealed (2.5kg and 5kg); polyethylene lined paper bags; stitched (25kg), containing free-flowing brown to tan coarse material.

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 Ltd
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4077

9. DATE OF FIRST AUTHORISATION

20th August 1993

10. DATE OF REVISION OF THE TEXT

August 2013

Approved: 07/08/2013