Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

LINCOCIN PREMIX

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg contains:

Active Substance

Lincomycin Hydrochloride	44.0 g
(equivalent to lincomycin base)	

Excipients

Liquid paraffin	10.0 g
*Microtracer FS-Blue/Natural Yellow (optional)	1-5 g

* Microtracer FS-Blue/Natural Yellow consists of stainless steel particulates coated with a mixture of Patent Blue V (E131) and Tumeric Food (E100) dyes.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Premix for medicated feed.

A pale brown coarse free-flowing powder

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.

4.3 Contraindications

Do not use in animals with known hypersensitivity to active ingredient.
Do not treat animals with lincomycin and erythromycin concurrently.
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 known.

4.5 Special precautions for use

Special precaution(s) for use in animals

Avoid inhaling dust and contact with skin.

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

Persons known to be hypersensitive to lincomycin and/or soyabean millfeed should not handle the product.
Care should be taken not to inhale dust. Wearing of dust masks and safety glasses is recommended during handling and mixing of the 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)

Occasionally pigs fed lincomycin may, within the first 2 days after onset of treatment, develop soft stools and/or mild swelling of the anus. On rare occasions some pigs may show skin irritation and mild irritable behaviour. These conditions are usually self-correcting within 5-8 days without discontinuing the 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, concurrent use is therefore not recommended.

4.9 Amounts to be administered and administration route

Oral via the feed.

For treatment of swine dysentery, the recommended dosage rate is 110g lincomycin per tonne of complete feed as the sole ration. Treatment should continue for three weeks or until clinical signs of disease (water, mucoid or bloody stools) disappear.

For control of swine dysentery, the recommended dosage rate is 44g lincomycin per tonne of complete feed as the sole ration.

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

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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: 24 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 active against a wide range of Gram-positive aerobic and anaerobic bacteria, anaerobic Gram-negative bacteria and mycoplasma. It is active against the primary causal agent of swine dysentery, *Serpulina hyodysenteriae*, and also the exacerbating anaerobes, Bacteroides, Fusobacterium and Clostridium spp.. Lincomycin has approximately 50% systemic bioavailability from oral administration in pigs and is significantly recirculated via the biliary route. At the recommended level, supra-MIC levels are achieved at the gastro-intestinal site of infection.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin
*Microtracer FS-Blue/Natural Yellow (optional)
Soybean millfeed

*Microtracer FS-Blue/Natural Yellow (optional) consists of stainless steel particulates coated with a mixture of Patent Blue V (E131) and Tumeric food (E100) dyes.

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 feed: 3 months.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Premix contained in polyethylene lined polyester or paper bags (2.5 or 25 kg).
Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland
Trading as Pfizer Animal Health
Ringaskiddy
Co. Cork

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/90/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT