SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Feed 110 mg/g premix for medicated feeding stuff for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg product contains:

Active substance:

Lincomycin (as hydrochloride) 110 g

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

White or almost white granules.

4. CLINICAL PARTICULARS

4.1 Target species

Swine.

4.2 Indications for use, specifying the target species

Swine: For treatment of swine dysentery caused by *Brachyspira hyodysenteriae,* mycoplasmal pneumonia associated with *Mycoplasma hyopneumoniae* and porcine proliferative enteropathy (ileitis) associated with *Lawsonia intracellularis*.

4.3 Contraindications

Do not administer with known hypersensitivity to the active substance or to the excipient.

Do not use in horses, ruminants, rabbits, guinea pigs and hamsters.

Do not use if resistance to lincosamides has been detected.

4.4 Special warnings for each target species

Inappropriate use of the product may increase the prevalence of bacteria resistant to lincosamides.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. The presence of the indicated diseases in the herd should be established before use.

4.5 Special precautions for use

i) Special precautions for use in animals

Medicated feeding stuff uptake can be affected by the severity of the disease. In case of insufficient uptake of feed, animals should be treated parenterally.

The product should only be used by approved medicated feed mills.

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

People with known hypersensitivity to lincomycin should avoid contact with the veterinary medicinal 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), gloves, overalls and safety glasses is recommended during the handling and mixing of this product.

Direct contact of the product with the skin, eyes and mucous membranes should be avoided.

In case of accidental exposure rinse abundantly with water. In case of allergic reaction (inflammation of the face, lips or eyes or respiratory difficulties) during handling or mixing of the product, seek medical advice immediately and show the package leaflet or the label to the physician.

Do not smoke, eat or drink when handling the product.

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

4.6 Adverse reactions (frequency and seriousness)

Lincomycin 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 skin reddening and mildly irritable behaviour. These conditions are usually self-correcting within 5-8 days without discontinuing lincomycin treatment.

4.7 Use during pregnancy, lactation

The safety of the product has not been established in pregnant or lactating sows. Use only in accordance with risk/benefit assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Co-administration with macrolides (e.g. erythromycin) should be avoided.

4.9 Amounts to be administered and administration route

To be administered orally, in dry medicated feeding stuff.

Indication	***Treatment (mg/kg feed)***	
	Linco-Feed 110 mg/g	***Lincomycin***
Swine dysentery	1000	110
Mycoplasma pneumonia	2000	220
Proliferative enteropathy	2000	220

Treatment of swine dysentery:

Feed 110 mg lincomycin/kg complete feed (equivalent to 5.5 mg lincomycin/kg bodyweight) as the sole ration for three weeks or until clinical signs of disease (watery, mucoid or bloody stools) disappear.

Treatment of mycoplasmal pneumonia:

Feed 220 mg lincomycin/kg complete feed (equivalent to 11 mg lincomycin/kg bodyweight) as the sole ration for three weeks or until clinical signs of disease disappear.

Treatment of porcine proliferative enteropathy:

Feed 220 mg lincomycin/kg complete feed (equivalent to 11 mg lincomycin/kg bodyweight) as the sole ration for three weeks.

Medicated feed may be pelleted at temperatures not exceeding 85^{o}C.

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

In pigs treated with 2-10 times the recommended dose orally for 14 days altered the stool consistency, from loose stool to diarrhoea, without the loss of appetite.

If suspected toxic reactions occur due to overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

4.11 Withdrawal period(s)

Swine: Meat and offal: 5 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: lincosamides, ATCvet code: QJ01FF02.

5.1 Pharmacodynamic properties

Lincomycin is a lincosamide antibiotic produced by *Streptomyces lincolensis*. Lincomycin is bacteriostatic in action inhibiting the protein synthesis predominantly by binding to the 50S ribosomal subunits of bacteria.

Depending on the sensitivity of micro-organisms, and on the concentration of the active substance the protein synthesis inhibition antibacterial action can either be bacteriostatic or bactericide.

Lincomycin is active against a wide range of Gram-positive bacteria, such as *staphylococci*, *streptococci*, β-haemolytic *streptococci*, c*orynebacteria*, *Erysipelothrix spp.*, and anaerobic bacteria, such as *clostridia*, *Bacteroides spp.*, *Brachyspira spp.*, as well as *Leptospira spp.* and *Mycoplasma spp.*

Lincomycin has no activity against Gram-negative bacteria, such as *Klebsiella spp.*, *Pasteurella spp.*, and *Salmonella spp.*

The resistance rate against lincomycin is slow, multiple-step type. Plasmid mediated infectious resistance is also described.

No cross-resistance has been described with penicillin, ampicillin, cephalosporins, tetracyclines, or novobiocin.

Lincomycin MIC_{90} (µg/ml) values are the followings:

Mycoplasma hyopneumoniae: MIC_{90} (µg/ml) = 0.25

Brachyspira hyodysenteriae: MIC_{90} (µg/ml) = 100

5.2 Pharmacokinetic particulars

Systemic bioavailability of lincomycin is approximately 53% after oral administration in pigs

Lincomycin is rapidly absorbed orally and reaches therapeutic plasma concentration.

After a single, oral administration of approximately 4.4 mg/kg and 11 mg/kg lincomycin to pigs resulted therapeutic plasma concentration for 12-16 hours, reaching peak plasma concentration after 4 hours. After a single, oral dose of 10 mg/kg lincomycin to pigs the maximum plasma concentration (C_{max}) of 1.45 mg/kg was reached at 3.6 hours (T_{max}). The elimination half life ($T_{1/2\beta}$) is about 3.36 hours. The oral administration of 22 mg/kg lincomycin for 3 days to pigs did not result in drug accumulation after 24 hours of administration and there was no therapeutic plasma concentration.

After oral administration the absorbed lincomycin is eliminated through the bile and faeces in active form or as metabolites.

Lincomycin is also excreted in the milk.

Lincomycin reaches the inflammation site by polymorf neutrophil granulocytes that explains its fast absorption and distribution, efficient penetration and targeted activity in difficult to reach tissues.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate.

6.2 Incompatibilities

None known.

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: 3 months.
Shelf-life after incorporation into feed: 3 months.

6.4. Special precautions for storage

Store in a dry place not exceeding 25°C.
Store in the original container tightly closed after use in order to protect from moisture.

6.5 Nature and composition of immediate packaging

5 kg multiwalled, polyethylene layered paper bag.
10 kg multiwalled, polyethylene layered paper bag.
25 kg multiwalled, polyethylene layered paper bag.
Not all pack sizes may be marketed.

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

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

Lavet Pharmaceuticals Ltd.
1161 Budapest
Ottó u. 14.
Hungary

8. MARKETING AUTHORISATION NUMBER

Vm 32823/4004

9. DATE OF FIRST AUTHORISATION

11 February 2011

10. DATE OF REVISION OF THE TEXT

February 2011

PROHIBITION OF SALE, SUPPLY AND/OR USE

At the final mixing-in the medicated feeding stuff the official guidelines should be taken into account.