SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Sol 400 mg/g powder for use in drinking water for pigs and chickens
(in Cyprus, Czech Republic, Greece, Hungary, Italy, Lithuania, Portugal, Romania, Slovakia and United Kingdom)

LincoScan 400 mg/g powder for use in drinking water for pigs and chickens
(in Poland)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Lincomycin (as hydrochloride) 400 mg/g

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for use in drinking water.
White or almost white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Swine and chicken (broiler)

4.2 Indications for use, specifying the target species

Treatment of infection caused by mycoplasma and bacteria susceptible to lincomycin for example:
Pigs: swine dysentery caused by *Brachyspira hyodysenteriae* and mycoplasma pneumonia associated with *Mycoplasma hyopneumoniae*.
Chicken: necrotic enteritis caused by *Clostridium perfringens.*

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to the excipient.
Do not use if resistance to lincosamides has been detected.
Do not administer to horses, ruminants, guinea pigs, hamsters, chinchilla and rabbits. Ingestion by these species may result in severe gastrointestinal effects.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. *Special precautions for use in animals*

Medicated drinking water uptake can be affected by the severity of the disease. In case of insufficient uptake of water, animals should be treated parenterally.
Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to lincomycin and may decrease the effectiveness of treatment with other lincosamides, macrolides or streptogramins due to potential for cross-resistance.

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 and safety glasses is recommended whilst reconstituting or administering the solution.
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 reconstituting or administering 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.

Other precautions
When spreading the manure of weaner pigs treated with the veterinary medicinal product at a dose of 10 mg/kg for 21 days, a minimum distance to surface water of 10 m should be applied.

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 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, egg laying

The safety of the veterinary medicinal product has not been established in pregnant or lactating sows. Use only in accordance with benefit/risk assessment by the responsible veterinarian. Do not use in birds in lay or within 4 weeks before the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use together with macrolide antibiotics.

4.9 Amounts to be administered and administration route

Dosage:
Swine:
Swine dysentery: the daily dose is 10 mg lincomycin per kg of body weight for 10 days "or at least 5 days after clinical signs disappear".
Mycoplasma pneumonia: 10 mg lincomycin per kg of body weight for 21 days.
Chicken (boiler)
Necrotic enteritis caused by *Clostridium perfringens:* the daily dose is 5 mg lincomycin per kg of body weight for 7 days.
Administration:
To be administered orally, in the drinking water.
Swine:
The product should be administered continuously in the drinking water. In pigs, administration of 33 mg lincomycin per litre containing to the completion of drinking water by dissolving 100 g of product in 1200 litres of water. When using a water proportioner, prepare a stock solution by dissolving 100 g of product in 12 litres of water. Set the proportioner to deliver 10 ml of stock solution per litre of drinking water.
Chicken (broiler):
The concentration to be used depends on the actual body weight and the water consumption of the animals and can be calculated as follows:

.....mg product per kg body weight and day	x	Average chicken body weight (kg)	=....mg product per litre of drinking water
Average daily water intake (litre/animal)			

To ensure a correct dosage body weight should be determined as accurately as possible. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of Lincomycin has to be adjusted accordingly. The medicated water should be the only source of drinking water, throughout the treatment period. Medicated water should be refreshed every 24 hours.

4.10 Overdose (symptoms, emergency procedures, antidotes)

Lincomycin has a good margin of safety, but higher levels of dosage than recommended may cause diarrhoea and loose stools in pigs.

4.11 Withdrawal period(s)

Meat and offal of swine: 0 day
Meat and offal of chicken (broiler): 5 days
Not authorised for use in laying birds producing eggs for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: lincosamide antibiotic, 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 micro-organisms, including also anaerobic bacteria such as *clostridia* and *Brachyspira spp.*, as well as *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

In absence of compatibility studies this product must not be mixed with other veterinary products.

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 dilution or reconstitution according to directions: 24 hours

6.4. Special precautions for storage

Do not store above 25°C.
Store in the original container tightly closed in order to protect from moisture.

6.5 Nature and composition of immediate packaging

150 g polypropylene container with polypropylene lid and inner bag of LDPE.
1.5 kg polypropylene container with polypropylene lid and inner bag of LDPE.
5 kg polypropylene container with polypropylene lid and inner bag of LDPE.
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

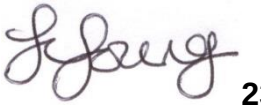
Vm 32823/4005

9. DATE OF FIRST AUTHORISATION

Date: 11 February 2011

10. DATE OF REVISION OF THE TEXT

Date: May 2013

Approved:  **23/05/2013**