PARTICULARS TO APPEAR ON THE OUTER PACKAGE {150 g and 1.5 kg bag}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincoral-S 222 mg/g + 444.7 mg/g powder for use in drinking water for pigs and chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Active substances:
Lincomycin 222 mg
(equivalent to 251.7 mg of lincomycin hydrochloride monohydrate)
Spectinomycin 444.7 mg
(equivalent to 672.4 mg of spectinomycin sulfate tetrahydrate)

3. PACKAGE SIZE

150 g
1.5 kg

4. TARGET SPECIES

Pigs and chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

7. WITHDRAWAL PERIODS

Withdrawal period:

Pigs:
Meat and offal: Zero days.

Chickens:
Meat and offal: 5 days.
Not for use in birds producing or intended to produce eggs for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 6 months
Once dissolved, use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Keep the bags tightly closed

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBER

Vm 30282/5017

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Lincoral-S 222 mg/g + 444.7 mg/g powder for use in drinking water for pigs and chickens

2. Composition

Each gram contains:

Active substances:

Lincomycin	222 mg
(equivalent to 251.7 mg of lincomycin hydrochloride monohydrate)	
Spectinomycin	444.7 mg
(equivalent to 672.4 mg of spectinomycin sulfate tetrahydrate)	

White to almost white powder for use in drinking water.

3. Target species

Pigs and chickens.

4. Indications for use

Pigs
For the treatment and metaphylaxis of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis*, and associated enteric pathogens (*Escherichia coli*).
The presence of the disease in the group must be established before the veterinary medicinal product is used.

Chickens
For the treatment and metaphylaxis of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* and *Escherichia coli* and associated with a low mortality rate.
The presence of the disease in the group must be established before the veterinary medicinal product is used.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or any of the excipients.
Do not use in cases of hepatic dysfunction.
Do not allow rabbits, rodents (e.g. chinchillas, hamsters, guinea pigs), horses or ruminants access to water or feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.
Do not use in laying hens.

6. Special warnings

Special warnings:
In *E. coli*, a significant number of the strains show high MIC values (minimum inhibitory concentrations) against the lincomycin-spectinomycin combination and may be clinically resistant, although no breakpoint is defined.
Due to technical constraints, the susceptibility of *L. intracellularis* is difficult to test in vitro, and data about the lincomycin-spectinomycin resistance status in that species are lacking.

Special precautions for safe use in the target species:
It is sound clinical practice to base treatment on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of target bacteria.
Use of the veterinary medicinal product deviating from the instructions in the SPC may increase the risk of development and selection of resistant bacteria and decrease the effectiveness of treatment with macrolides due to the potential for cross-resistance.
The oral use of preparations containing lincomycin is only indicated in swine and chickens.
Do not leave access to the medicated water for other animals. Lincomycin may lead to severe gastrointestinal disturbances in other animal species.
The repeated or prolonged use should be avoided, by improving the farm management and disinfection practices
Diagnosis should be reconsidered if improvement is not seen after 5 days.
Sick animals have a reduced appetite and an altered drinking pattern, and severely affected animals may therefore require parenteral treatment.
This powder is for use in drinking water only and should be dissolved before use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Lincomycin and spectinomycin may cause hypersensitivity (allergy) following inhalation, ingestion or skin contact. Allergic reactions to these substances may occasionally be serious.
People with known hypersensitivity to lincomycin and/or spectinomycin should avoid contact with the veterinary medicinal product.
This veterinary medicinal product contains lincomycin and spectinomycin, which may be harmful to the unborn child. Pregnant women should use this veterinary medicinal product with caution.
Skin and eye contact with the powder and the medicated drinking water should be avoided.
This product may cause eye and respiratory irritation.
Handle this product with great care to avoid exposure, taking all recommended precautions.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 (FFP2 in general, FFP3 for pregnant women) or a non-disposable respirator to European Standard EN140 with a filter to ENl43.
Wear gloves and safety glasses during preparation of medicated water and wash any exposed skin immediately after handling the product.
In the event of eye contact, rinse the affected area with large amounts of clean water.

If symptoms such as skin rash, persistent cough, or persistent eye irritation appear after exposure, seek medical advice immediately and show the package leaflet or label to the physician.

Special precautions for the protection of the environment:
The use of this product poses a risk to aquatic organisms, terrestrial plants, groundwater ecosystems and to human health through consumption of groundwater.
To prevent environmental risks, manure from treated animals must not be spread onto land without dilution with manure from untreated animals. Prior to spreading to land or trading, one part manure from treated animals should be diluted with at least three parts manure from untreated animals, and once spread, soil must be ploughed to a depth of at least 20 cm.
This product should only be used during three production cycles of broilers a year.
The product should not come in contact with water bodies.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in dogs and rats have not produced any evidence of reproductive, foetotoxic or teratogenic effects for lincomycin or spectinomycin.
Lincomycin is excreted in milk.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Laying birds:
Do not use in birds in lay.

Interaction with other medicinal products and other forms of interaction:
The combination of lincosamides and macrolides is antagonistic, due to competitive binding to their target sites. Combination with anaesthetics may lead to possible neuromuscular blockade.
Do not administer with kaolin or pectin as they impair lincomycin absorption. If co-administration is mandatory, observe a delay of two hours between administrations.

Overdose:
In the event of overdose in pigs, a change in the consistency of the faeces (soft faeces and/or diarrhoea) may be observed.
In chickens treated at several times the recommended dose, enlargement of the caecum and abnormal caecum content was observed.
In case of accidental overdose, the treatment should be interrupted and restarted at the recommended dose.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Pigs and chickens:

Rare (1 to 10 animals / 10,000 animals treated)	Irritability, Excitation Rash, Pruritus Allergic reaction[1], Hypersensitivity reaction[1]
Undetermined frequency (cannot be estimated from the available data)	Diarrhea[2], Soft stool[2], Perianal inflammation[2]

[1] Use of the product should be stopped and symptomatic treatment must be implemented.
[2] Have been encountered in healthy pigs at the start of the treatment. The symptoms disappeared within 5 to 8 days without interruption of the treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

In drinking water use.
The recommended dosage rates are:

Pigs: 3.33 mg lincomycin and 6.67 mg spectinomycin/kg bw/day, for 7 days. This amounts to 15 mg veterinary medicinal product/kg bw/day for 7 days.

Chickens: 16.65 mg lincomycin and 33.35 mg spectinomycin/kg bw/day, for 7 days. This amounts to 75 mg veterinary medicinal product/kg bw/day for 7 days.

Treatment should be initiated as soon as first clinical signs occur.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of lincomycin and spectinomycin may need to be adjusted accordingly.

To ensure a correct dosage body weights should be determined as accurately as possible.

The use of suitability calibrated measuring equipment is recommended.
Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{mg veterinary medicinal product / kg body weight day} \times \text{Average body weight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \text{mg veterinary medicinal product per litre of drinking water}$$

9. Advice on correct administration

The medicated drinking water should be the sole source of drinking water for the treatment duration. Only sufficient medicated drinking water should be prepared to cover the daily requirements. Medicated drinking water should be refreshed or replaced every 24 hours. The maximum solubility of the veterinary medicinal product in soft/hard water is 90 g/L at 20°C and 70 g/L at 5°C.
When using a water tank, it is recommended to prepare a stock solution and to dilute it to the target final concentration. The stock solutions should be replaced every 24 hours. Turn off the water supply to the tank until all the medicated solution is consumed.
When using a proportioner, adjust flow rate settings of the dosing pump according to the concentration of the stock solution and water intake of the animals to be treated. Care should be taken that the intended dose will be completely ingested.
After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

10. Withdrawal periods

Pigs:
Meat and offal: Zero days.

Chickens:
Meat and offal: 5 days.
Not for use in birds producing or intended to produce eggs for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the bags tightly closed.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dissolution according to directions: 24 hours

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as lincomycin and spectinomycin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 30282/5017

Pack sizes:
Bag of 150 g
Bag of 1.5 kg

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release:
HUVEPHARMA SA
34 rue Jean Monnet
Z.I. d'Etriché
Segré
49500 Segré-en-Anjou Bleu
France

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Spectinomycin is classified as very persistent in the environment and is known to be toxic to terrestrial plants, cyanobacteria, and groundwater ecosystems.
Lincomycin is known to be toxic to cyanobacteria and groundwater ecosystems.

POM-V

Gavin Hall

Approved: 23 June 2025