SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincoral-S 222 mg/g + 444.7 mg/g powder for use in drinking water (AT, BE, BG, CY, CZ, EL, HR, HU, IE, IS, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK)

Lincoral-S (DK, EE)

Lincoral 222 mg/g + 444.7 mg/g powder for use in drinking water (ES)

2. QUALITATIVE AND QUANTITATIVE 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)	

Excipient:

Qualitative composition of excipients and other constituents
Lactose monohydrate

White to almost white powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs and chickens.

3.2 Indications for use for each target species

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.

3.3 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.

3.4 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.
Cross-resistance has been shown between lincomycin and different antimicrobials including other lincosamides, macrolides and streptogramin B. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to lincosamides, macrolides or streptogramin B because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
This antimicrobial combination should only be used where diagnostic testing has indicated the need for simultaneous administration of each of the active substances.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG (Antimicrobial Advice Ad Hoc Expert Group) category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
Not for use for prophylaxis.
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.
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:
This veterinary medicinal product contains lincomycin, which may be harmful to the unborn child. Pregnant women should use this veterinary medicinal product with great caution.
This veterinary medicinal product contains lincomycin, spectinomycin and lactose monohydrate, all of which can cause allergic reactions in some people. People with known hypersensitivity to lincomycin, spectinomycin or lactose monohydrate should avoid contact with the veterinary medicinal product.
The veterinary medicinal product may be harmful when inhaled before being diluted in drinking water. Care should be taken not to raise and inhale any dust.
This veterinary medicinal product may cause skin and eye irritation. Contact with skin and eyes should be avoided.
Handle this veterinary medicinal product with great care to avoid skin and ocular exposure.

Wear gloves, safety glasses and 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 conform to EN143 during preparation of medicated water.

Wash hands and any exposed skin with soap and water immediately after use. In the event of eye contact, rinse the affected area with large amounts of clean water.

If you develop symptoms following exposure such as a skin rash or persistent eye irritation, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of environment:
The use of the veterinary medicinal product poses a risk to aquatic and terrestrial organisms, groundwater ecosystem and to human health through consumption of groundwater. The veterinary medicinal product should not come in contact with water bodies.

3.6 Adverse events

Pigs:

Rare (1 to 10 animals / 10,000 animals treated)	Allergic reaction[1], hypersensitivity reaction[1] Irritability, excitation Rash, pruritus
Undetermined frequency (cannot be estimated from the available data)	Diarrhea[2], loose stool[2], perianal inflammation[2]

[1] Treatment should be stopped, and symptomatic treatment implemented.
[2] In healthy pigs at the start of the treatment. Symptoms resolved within 5 to 8 days without interruption of the treatment.

Chickens:

Rare (1 to 10 animals / 10,000 animals treated)	Allergic reaction[1], hypersensitivity reaction[1]

[1] Treatment should be stopped, and symptomatic treatment implemented.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation and lay.

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 or in replacement chicks which are intended to produce eggs for human consumption.

3.8 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.

3.9 Administration routes and dosage

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.
To ensure a correct dosage body weights 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 and spectinomycin may need to be adjusted accordingly.
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:

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

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. 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

Animals must not be slaughtered for human consumption during treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QJ01FF52

4.2 Pharmacodynamics

The veterinary medicinal product is a combination of two antibiotics, lincomycin and spectinomycin, having a complementary spectrum of activity.

Lincomycin
Lincomycin is a lincosamide antibiotic with primarily bacteriostatic activity, but at high concentrations it may have a bactericidal effect. It has a mechanism of action and bacterial spectrum similar to the macrolides. Lincomycin acts by binding to the 50S ribosomal subunit and inhibiting bacterial protein synthesis.
Lincomycin is active against gram-positive bacteria, some anaerobic gram-negative bacteria and mycoplasmas. It has little or no action against gram-negative bacteria such as *Escherichia coli*.
Resistance to lincomycin is most often due to methylation of specific nucleotides in the 23S ribosomal RNA component of the 50S ribosomal subunit, which prevents drug binding to the target site. The rRNA methylases are encoded by different erythromycin-resistant methylase (erm) genes that can be horizontally transferred.
This mechanism of target site modification can confer cross-resistance to macrolides, other lincosamides, and streptogramins B (i.e., MLSB phenotype).

Spectinomycin
Spectinomycin is an aminocyclitol antibiotic derived from *Streptomyces spectabilis*, that has bacteriostatic activity and is active against *Mycoplasma* spp. and some gram-negative bacteria such as *E. coli*.
Spectinomycin acts by binding to the 30S subunit of the bacterial ribosome and inhibiting protein synthesis.
The mechanism by which orally administered spectinomycin acts on pathogens at the systemic level despite poor absorption is not fully elucidated, and might rely partly on indirect effects on the gut flora.
In *E. coli* the MIC distribution appears to be bimodal, with a significant number of strains showing high MIC values; this could partly correspond to natural (intrinsic) resistance.
In vitro studies as well as clinical efficacy data show that the lincomycin-spectinomycin combination is active against *Lawsonia intracellularis.*
Resistance to spectinomycin is commonly due to enzymatic inactivation of the drug by adenylylation. Enzymes that can adenylylate spectinomycin and streptomycin may confer combined resistance to both antimicrobials.

4.3 Pharmacokinetics

Lincomycin

In pigs, lincomycin is rapidly absorbed following oral administration. A single oral administration of lincomycin hydrochloride, at dose levels of approximately 22, 55 and 100 mg/kg body weight in pigs, resulted in dose related lincomycin serum levels, detected for 24–36 hours after administration. Peak serum levels were observed at 4 hours after dosing. Similar results were observed following single oral doses of 4.4 and 11.0 mg/kg body weight in pigs. Levels were detectable for 12 to 16 hours, with peak concentrations occurring at 4 hours. A single oral dose of 10 mg/kg body weight was administered to pigs to determine the bioavailability. The oral absorption of lincomycin was found to be 53% ± 19%.
Repeated dosing of pigs with daily oral doses of 22 mg lincomycin/kg body weight for 3 days indicated no accumulation of lincomycin in the species, with no detectable serum levels of antibiotic after 24 hours post administration.
Lincomycin pharmacokinetic studies in pigs show that lincomycin is bioavailable when given intravenously, intramuscularly or orally. The average of the half-lives of elimination of all routes of administration is 2.82 hours in pigs.
In chickens treated with the veterinary medicinal product in drinking water at the target dose of 50 mg/kg body weight of total activity (at a ratio of 1:2 lincomycin:spectinomycin) for seven consecutive days, C_{max} after first offering of medicated water was calculated to be 0.0631 µg/ml. C_{max} occurred at 4 hours after introduction of the medicated water.

Spectinomycin
Studies performed in various animal species have demonstrated that spectinomycin undergoes limited absorption from the intestine (less than 4–7%) after oral administration. Spectinomycin exhibits little tendency to protein binding and is poorly liposoluble.

Environmental properties

Spectinomycin is classified as very persistent in the environment.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after a first opening the immediate packaging: 6 months
Shelf life after dissolution according to directions: 24 hours.
Medicated drinking water should be refreshed or replaced every 24 hours.

5.3 Special precautions for storage

Keep the bags tightly closed.
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

150 g thermos-sealed sachets made of polyethylene/aluminum/polyethylene/paper
1.5 kg thermos-sealed bags made of polyethylene/aluminum/polyester
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
The 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

HUVEPHARMA NV

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
150 g sachet: polyethylene/aluminium/polyethylene/paper
1.5 kg bags: polyethylene/aluminum/polyester

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincoral-S 222 mg/g + 444.7 mg/g powder for use in drinking water (IE, AT, BE, BG, CY, CZ, EL, HR, HU, IE, IS, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK)

Lincoral-S (DK, EE)

Lincoral 222 mg/g + 444.7 mg/g powder for use in drinking water (ES)

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

In drinking water use.

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.

Animals must not be slaughtered for human consumption during treatment.

8. EXPIRY DATE

Exp.
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 NUMBERS

15. BATCH NUMBER

Lot {number}

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 (AT, BE, BG, CY, CZ, EL, HR, HU, IE, IS, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK)
Lincoral-S (DK, EE)
Lincoral 222 mg/g + 444.7 mg/g powder for use in drinking water (ES)

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.

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.

Cross-resistance has been shown between lincomycin and different antimicrobials including other lincosamides, macrolides and streptogramin B. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to lincosamides, macrolides or streptogramin B because its effectiveness may be reduced.

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
This antimicrobial combination should only be used where diagnostic testing has indicated the need for simultaneous administration of each of the active substances.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG (Antimicrobial Advice Ad Hoc Expert Group)category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Not for use for prophylaxis.
Use of the veterinary medicinal product deviating from the instructions in the package leaflet 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.
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:
This veterinary medicinal product contains lincomycin, which may be harmful to the unborn child. Pregnant women should use this veterinary medicinal product with great caution.
This veterinary medicinal product contains lincomycin, spectinomycin and lactose monohydrate, all of which can cause allergic reactions in some people. People with known hypersensitivity to lincomycin, spectinomycin or lactose monohydrate should avoid contact with the veterinary medicinal product.
The veterinary medicinal product may be harmful when inhaled before being diluted in drinking water. Care should be taken not to raise and inhale any dust.
This veterinary medicinal product may cause skin and eye irritation. Contact with skin and eyes should be avoided.
Handle this veterinary medicinal product with great care to avoid skin and ocular exposure.
Wear gloves, safety glasses and 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 conform to EN143 during preparation of medicated water.
Wash hands and any exposed skin with soap and water immediately after use.
In the event of eye contact, rinse the affected area with large amounts of clean water. If you develop symptoms following exposure such as a skin rash or persistent eye irritation, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
The use of the veterinary medicinal product poses a risk to aquatic and terrestrial organisms, groundwater ecosystem and to human health through consumption of groundwater. The veterinary medicinal 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:
The safety of the veterinary medicinal product has not been established during lay.
Do not use in birds in lay or in replacement chicks which are intended to produce eggs for human consumption.

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:

Rare (1 to 10 animals / 10,000 animals treated)	Allergic reaction[1], hypersensitivity reaction[1] Irritability, excitation Rash, pruritus
Undetermined frequency (cannot be estimated from the available data)	Diarrhea[2], loose stool[2], perianal inflammation[2].

[1] Treatment should be stopped, and symptomatic treatment implemented.
[2] In healthy pigs at the start of the treatment. Symptoms resolved within 5 to 8 days without interruption of the treatment.

Chickens:

Rare (1 to 10 animals / 10,000 animals treated)	Allergic reaction[1], hypersensitivity reaction[1]

[1] Treatment should be stopped, and symptomatic treatment implemented.

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 {national system details}.

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.
To ensure a correct dosage body weights 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 and spectinomycin may need to be adjusted accordingly.
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:

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

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. 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.

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.

10. Withdrawal periods

Pigs:
Meat and offal: Zero days.

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

Animals must not be slaughtered for human consumption during treatment.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bags tightly closed.

Do not use this veterinary medicinal product after the expiry date which is stated on the sachet/bag, 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 or household waste.
The 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

150 g thermos-sealed sachets made of polyethylene/aluminum/polyethylene/paper
1.5 kg thermos-sealed bags made of polyethylene/aluminum/polyester

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
HUVEPHARMA NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 292 83 05 or +32 3 288 18 49
pharmacovigilance@huvepharma.com

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

Local representative and contact details to report suspected adverse reactions:

17. Other information

Spectinomycin is classified as a very persistent substance in the environment.