

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottles containing 150 g or 1.5 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Spectin 100, 222/444.7 mg/g Powder for use in drinking water for pigs and chickens
lincomycin (as lincomycin hydrochloride)/spectinomycin (as spectinomycin sulphate)

2. STATEMENT OF ACTIVE SUBSTANCES

Lincomycin (as lincomycin hydrochloride)	222 mg/g
Spectinomycin (as spectinomycin sulphate)	444.7 mg/g.

3. PHARMACEUTICAL FORM

Powder for use in drinking water

4. PACKAGE SIZE

150 g
1.5 kg

5. TARGET SPECIES

Pigs and chickens

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For use in drinking water.
Read the package leaflet before use.

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Shelf life after first opening the immediate packaging: 6 months

Shelf life after dilution according to directions: 24 hours.

Any medicated water which is not consumed within 24 hours should be discarded.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer: Zoetis Belgium SA, Rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium.

Procured from within the EU and repackaged by
Kernfarm B. V., De Corridor 14D 3621 ZB Breukelen, The Netherlands.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43877/4001

17. MANUFACTURER’S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Linco-Spectin 100, 222/444.7 mg/g Powder for use in drinking water for pigs and chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

Manufacturer responsible for batch release:

Zoetis Belgium SA, rue Laid Burniat 1, 1348 Louvain-La-Neuve, Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Spectin 100, 222/444.7 mg/g powder for use in drinking water for pigs and chickens

Lincomycin, spectinomycin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each g contains:

Active substances:

Lincomycin (as lincomycin hydrochloride)	222 mg
Spectinomycin (as spectinomycin sulphate)	444.7 mg

Excipients:

Sodium benzoate, lactose.

4. INDICATION(S)

Pigs

For the treatment and metaphylaxis of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis*, and associated enteric pathogens (*Escherichia coli*) susceptible to lincomycin and spectinomycin.

The presence of the disease in the group must be established before the product is used.

Chickens

For the treatment and metaphylaxis of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to lincomycin and spectinomycin, and associated with a low mortality rate.

The presence of the disease in the flock must be established before the product is used.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substances or any of the excipients.

Do not use in case 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. ADVERSE REACTIONS

Cases of diarrhoea or soft faeces and/or perianal region inflammation have been encountered in healthy pigs at the start of treatment. The symptoms disappeared within 5 to 8 days without interruption of the treatment. Rare cases of irritability/excitation, skin rash/pruritus were also observed.

Allergic/hypersensitive reactions are rare but can occur and require stopping treatment with the veterinary medicinal product. A symptomatic treatment must be implemented.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs and chickens

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For use in drinking water.

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 powder/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 powder/kg bw/day for 7 days.

Treatment should be initiated as soon as first symptoms occur.

For the preparation of drinking water, the incorporation rate of the veterinary medicinal product in water will depend on the body weight of the animals and their actual daily intake of water.

To ensure a correct dosage and avoid underdosing, mean body weights in the group of animals and daily water consumption should be determined as accurately as possible.

The medicated drinking water should be the sole source of drinking water for the treatment duration. Medicated water should be removed every day and replaced by a new solution.

In case of disease accompanied with significant decrease in water intake, parenteral treatment may have to be initiated.

Use the following indications as a basis for the precise calculation of incorporation rate of the veterinary medicinal product in drinking water.

Pigs:

To determine the volume of dilution (in litres of drinking water) required for 150 g of the veterinary medicinal product, use the following formula:

$$\text{Volume (L) for 150 g of the veterinary medicinal product} = \frac{10,000 \times [\text{daily water consumption per animal (L)}]}{\text{average body weight of one pig (kg)}}$$

In pigs 150 g of the veterinary medicinal product corresponds to the dose for 10,000 kg of body weight per day.

As an indication, standard water intake varies around 0.15 L/kg bw/day. The table below shows the volume of water to be used for dilution of 150 g of the veterinary medicinal product.

Water consumption	150 g of powder = 100 g antibiotic activity should be diluted in...
0.1 L/kg bw/day	1,000 L of drinking water
0.15 L/kg bw/day	1,500 L of drinking water
0.2 L/kg bw/day	2,000 L of drinking water
0.25 L/kg bw/day	2,500 L of drinking water

Chickens:

To determine the volume of dilution (in litres of drinking water) for 150 g of the veterinary medicinal product, use the following formula:

$$\text{Volume (L) for 150 g of the veterinary medicinal product} = \frac{2,000 \times [\text{daily water consumption per bird (L)}]}{\text{average body weight of one bird (kg)}}$$

150 g of the veterinary medicinal product corresponds to the dose for 2,000 kg of body weight per day.

9. ADVICE ON CORRECT ADMINISTRATION

This powder is for use in drinking water only and should be dissolved before use. The medicated drinking water should be the sole source of drinking water for the treatment duration. Medicated water should be removed every day and replaced by a new solution.

The repeated or prolonged use should be avoided, by improving the farm management and disinfection practices.

The veterinary medicinal product should be used based on antimicrobial susceptibility testing. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the product deviating from the instructions given in the summary of product characteristics may increase the prevalence of bacteria resistant to lincomycin and spectinomycin and may decrease the effectiveness of treatment with other antimicrobials of the same or related classes, due to the potential for cross resistance.

Diagnosis should be reconsidered if improvement is not seen after 5 days.

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. 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 product does not require any special storage conditions.

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

Shelf life after first opening the immediate packaging: 6 months

Shelf life after dilution according to directions: 24 hours.

Any medicated water which is not consumed within 24 hours should be discarded.

12. SPECIAL WARNING(S)

Special warnings for each 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.

In *E. coli*, a significant part 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 use in animals:

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 and must be dissolved in water.

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

People with known hypersensitivity to lincomycin, spectinomycin or soybean millfeed should avoid contact with the veterinary medicinal product. Care should be taken not to raise and inhale any dust.

Contact with skin and eyes should be avoided.

Personal protective equipment consisting of approved dust masks (either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN 140 with a filter EN 143), gloves and safety glasses should be worn when handling and mixing the product.

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

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

Pregnancy and lactation:

Pigs

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 accordingly to benefit-risk assessment by the responsible veterinarian.

Lay:

Chickens

Do not use in birds in lay.

Interaction with other medicinal products and other forms of interaction:

In general mixture with other medicines should be avoided.

The combination of lincosamides and macrolides is antagonistic, due to competitive binding to their target sites. Combination with anaesthetics may lead to possible neuromuscular blocking.

Do not administer with kaolin or pectin as they impair lincomycin absorption. If co-administration is mandatory, respect a delay of two hours between intakes.

Overdose (symptoms, emergency procedures, 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.

Treatment is symptomatic. In case of accidental overdose, the treatment should be interrupted and restarted at the recommended dose.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2021

15. OTHER INFORMATION

White high density polyethylene (HDPE) bottle containing 1.5 kg powder for use in drinking water with a white tamper evident low density polyethylene (LDPE) lid.

White high density polyethylene (HDPE) bottle containing 150 g powder for use in drinking water with a white tamper evident low density polyethylene (LDPE) lid with an aluminium cap.

Not all pack sizes may be marketed.

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

Approved 08 January 2021

