

PACKAGE LEAFLET

FOR ANIMAL TREATMENT ONLY

LINCOVET-S

powder for oral solution lincomycin and spectinomycin for 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:

PROVET S.A.

120 Eleftherias Avenue, Eleousa, Zitsa, 45500 Ioannina, Greece

Tel.: +30 2105508500, +30 2105575770-3

E-mail: vet@provet.gr

Manufacturer responsible for batch release:

PROVET S.A. (FACTORY)

Nikiforou Foka & Ag. Anargyron, Thesi Vrago,

193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT LINCOVET-S

Powder for oral solution

Lincomycin + Spectinomycin

(33.3 + 66.7)g/150g

For chickens

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

150 g of products contain:

Active substances:

Lincomycin hydrochloride monohydrate

(equivalent to Lincomycin) 33.3g

Spectinomycin sulfate tetrahydrate

(equivalent to Spectinomycin) 66.7g

Excipients: Sodium benzoate

4. INDICATIONS

Hens: For the treatment and prevention of Chronic Respiratory Disease (C.R.D.) caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to lincomycin and spectinomycin and correlated with a low mortality rate. There should be evidence about the presence of infection in the animals before the use of the product.

5. CONTRAINDICATIONS

Do not use in laying hens.

Do not use in hamsters, rabbits, guinea pigs, chinchillas, horses and ruminating animals.

6. ADVERSE REACTIONS

The use of LINCOVET-S powder for oral solution, as of any other antimicrobial, may sometimes cause overgrowth of resistant microorganisms, such as yeasts. In such cases, appropriate measures must be taken.

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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

Chickens

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

Administer via the drinking water.

The recommended doses are:

Hens: 16.65 mg lincomycin and 33.35 mg spectinomycin/ kg b.w. per day, for 7 days.

9. ADVICE ON CORRECT ADMINISTRATION

The solution should be prepared daily in order to be fresh.

10. WITHDRAWAL PERIOD

Meat and offal: 5 days

Do not use in animals producing eggs for human consumption, including breeding chicks intended to produce eggs for human consumption.

Animals should not be slaughtered for human consumption during treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store at a temperature below 25°C, protected from light.

Shelf-life after dilution in drinking water according to directions: 48 hours

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

12. SPECIAL WARNINGS

Special warnings for each target species

Regarding *E. coli*, a great number of strains shows high MIC (minimum inhibitory concentration) values in comparison with the combination of lincomycin and spectinomycin and it may probably be clinically resistant, although no sensitivity limit has been established.

Special precautions for use in animals

In feedingstuff industries, which produce feed for ruminants, the mill should be thoroughly cleaned, because lincomycin residues may cause damage of the microbial flora that causes acetonaemia.

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

Care should be taken to avoid the inhalation of the dust of the product. The use of facial mask is recommended during the mixture and administration of the product. Skin contact should be avoided. Hands and exposed skin should be washed after handling the product.

Lay

Do not use in laying hens

Interaction with other medicinal products and other forms of interaction

It has been proven that the combination of lincomycin and spectinomycin is clinically compatible with salinomycin.

Overdose (symptoms, emergency procedures, antidotes)

None reported

Incompatibilities

None known

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

Ask your veterinary surgeon 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
DECEMBER 2019

15. OTHER INFORMATION

PACKAGE

Container of 150 g

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.

under veterinary medical prescription
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN