The following text is currently approved by the National Organization for Medicines (E.O.F.) in Greece and is subject to changes at any time.

### PACKAGE LEAFLET

For animal treatment only

## LINCOVET-S

injectable solution of lincomycin and spectinomycin for sheep

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER AND OF THE MANUFACTURING AUTHORIZATION 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: <u>vet@provet.gr</u>

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 Injectable solution Lincomycin + Spectinomycin (50 + 100) mg/ml

(50 + 100) mg/ml Sheep

### 3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml of solution contains:
Active substances: 50 mg Lincomycin base (as hydrochloride), 100 mg Spectinomycin base (as sulfate tetrahydrate)
Excipients: Benzyl alcohol, Water for injection

### 4. INDICATIONS

LINCOVET-S injectable solution is indicated for the treatment of pneumonia and other respiratory infections caused by bacteria and mycoplasma. It is also indicated for the treatment of foot rot.

### **5. CONTRAINDICATIONS**

Do not use in animals with known sensitivity to lincomycin or spectinomycin. Lincomycin is toxic for lagomorphs, guinea pigs and chinchillas.

### 6. ADVERSE REACTIONS

Diarrhea or loose stools may be observed.

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

- very common (more than 1 in 10 animals displaying adverse reactions during one treatment)
- 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)

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 Sheep

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

Administer intramuscularly. 1 ml LINCOVET-S<sup>®</sup> inj. per 10 kg of b.w. (15 mg/ kg of b.w.) every 24 hours for 3 days

# 9. ADVICE ON CORRECT ADMINISTRATION None

## **10. WITHDRAWAL PERIOD**

Meat and offal: 15 days Milk: 60 hours (2.5 days, 5 milkings)

# **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children. Store below 25°C, in a dry place protected from light. Shelf life after first opening of the container: 30 days Do not use this veterinary medicinal product after the expiry date which is stated on the label/ box. The expiry date refers to the last day of that month.

### 12. SPECIAL WARNING(S)

<u>Pregnancy and lactation:</u> As there are no studies available, do not use during pregnancy and lactation.

### Interaction with other medicinal products and other form of interaction:

An antagonistic effect is shown to exist between lincomycin and erythromycin. For this reason concurrent administration of lincomycin and erythromycin should be avoided. Other interactions have not been mentioned.

<u>Overdose (symptoms, emergency procedures, antidotes):</u> No adverse reactions were observed in sheep, when a threefold and fivefold of the recommended dose was administrated intramuscularly for five consecutive days.

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** JUNE 2017

## **15. OTHER INFORMATION**

<u>PACKAGES</u> Vials of 50 ml, 100 ml, 200 ml and 250 ml Not all pack sizes may be marketed.

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

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