

PACKAGE LEAFLET

For animal treatment only

STOZZON-L tablets 300

Tablets of levamisole for sheep (meat producing)

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

STOZZON-L®

tablets

300mg/tab,

Levamisole

for Sheep

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each tablet contains:

Active substance: 300 mg Levamisole hydrochloride

Excipients: Lactose, Polyvinylpyrrolidone (PVP), Microcrystalline cellulose, Sodium starch glucolate, Talc, Magnesium stearate, Colloidal silicon dioxide, Alcohol

4. INDICATIONS

STOZZON-L® is a broad spectrum anthelmintic against nematodes. It is used for the prevention and treatment of gastrointestinal and pulmonary strongyloidiasis of sheep.

Particularly, levamisole is highly effective against mature (95-100%) and immature (85-95%) stages of the following species: *Haemonchus* spp., *Neoascaris vitulorum*, *Trichostrongylus* spp., *Chabertia ovina*, *Cooperia* spp., *Oesophagostomum* spp., *Nematodirus* spp., *Dictyocaulus* spp., *Marshallagia marshalli*, *Thelazia* spp. and *Bunostomum* spp.

Levamisole is very effective against strains of *Haemonchus contortus*, *Ostertagia circumcincta* and *Trichostrongylus* spp. resistant to benzimidazoles. However, some strains of these parasites might develop resistance against levamisole. This resistance does not cross with that of benzimidazoles.

Levamisole is 80% effective against mature and immature *Ostertagia* spp. Levamisole is partially effective (60-80%) against *Protostrongylus rufescens* and *Strongyloides papillosus*, even less (below 60%) against *Trichuris* spp. Levamisole is not effective against *Muellerius capillaris* and *Cystocaulus ocreatus*, as well against the sub-biotic L₄ larvae of *Ostertagia* spp. Levamisole has no killing effects.

5. CONTRAINDICATIONS

Administer levamisole with caution to animals with renal or hepatic insufficiency.

6. ADVERSE REACTIONS

Some animals may become agitated and exhibit stimulation and increased salivation within a few minutes after administration of the product.

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

Sheep (meat producing)

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

The general dosage of levamisole in sheep is 7.5 mg/ kg of b.w., specifically 1 tablet STOZZON-L[®] 300 tabs of 300 mg/ 40 kg of b.w.

Tablets are administered per os with a balling gun or by placing at the base of the tongue. No specific diet is required before administration.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD(S)

Meat: 7 days

Do not administer to sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a cool and dry place protected from light.

Shelf-life of the veterinary medicinal product as packaged for sale: 60 months

Do not use this veterinary medicinal product after the expiry date which is stated on the box.

The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

During vaccination against *Clostridia* spp., concurrent use of levamisole improves the titer of the induced antibody production.

Incompatibilities

Do not combine levamisole with carbon tetrachloride, hexachloroethane, hexachlorophene and bithionol sulfoxide 72 hours (3 days) after treatment, because these combinations are toxic.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTEMATERIALS, 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

MAY 2005

15. OTHER INFORMATION

PACKAGES

Box of 50 tablets in blister

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