

**MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET (5L, 2.5L and 1L label)**

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Levitape oral suspension for sheep

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

An oral suspension containing 18.8 mg/ml praziquantel and 37.5 mg/ml levamisole hydrochloride.

**4. PHARMACEUTICAL FORM**

Oral suspension.

**5. PACKAGE SIZE**

5.0 L

2.5 L

1 L

**6. INDICATIONS**

Read instructions carefully prior to use.

Broad spectrum anthelmintic for sheep.

Highly effective against mature and immature nematodes, including lungworms and against adult tapeworms.

**Uses**

Levitape is a broad spectrum anthelmintic for use in the treatment and control of roundworm, lungworm and tapeworm infections in sheep. It is highly effective against mature and developing immature forms of roundworms and lungworms and against adult forms of tapeworm. Levitape should be used in cases of parasitic gastro-enteritis and lungworm disease caused by those organisms sensitive to treatment with praziquantel and levamisole hydrochloride.

Stomach and Bowel Worms: *Bunostomum* spp, *Chabertia* spp, *Cooperia* spp, *Haemonchus* spp, *Nematodirus* spp, *Oesophagostomum* spp, *Ostertagia* spp, *Trichostrongylus* spp.

Lungworms: *Dictyocaulus* spp.

Tapeworms: *Monezia* spp.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test).

Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to levamisole has been reported in *Teladorsagia (Ostertagia)*, *Cooperia* and *Trichostrongylus* species in sheep in a number of countries including the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

## 7. CONTRAINDICATIONS

Do not use in sheep that are severely stressed or in ill-health. Animals must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.

## 8. ADVERSE REACTIONS

*Hazard Warnings*: At normal levamisole dose levels, sheep rarely show any side-effects. The effects of over-dosage are transient and include head shaking, salivation and slight muscle tremors.

The praziquantel component of Levitape poses no hazard to sheep at normal dose rates.

## 9. TARGET SPECIES

Sheep.

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

### Dosage and Administration

Levitape should be administered as an oral drench. Do not mix with other products. It should be well shaken before use. Dosing must be accurate, using a drenching gun.

The dose is 7.5 mg/kg levamisole hydrochloride and 3.75 mg/kg praziquantel given orally, equivalent to 1 ml per 5 kg bodyweight.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

### Dosage guide

Bodyweight (kg)	Dose (ml)	Doses per pack		
		5 litre	2.5 litre	1 litre
Up to 10 kg	2 ml	2500	1250	500
10-15 kg	3 ml	1666	833	333
16-20 kg	4 ml	1250	625	250
21-25 kg	5 ml	1000	500	200
26-30 kg	6 ml	833	416	166
above 31 kg add 1 ml per 5 kg				

### 11. ADVICE ON CORRECT ADMINISTRATION

Sheep drench.

For oral administration only.

Shake well before use.

### 12. WITHDRAWAL PERIOD

*Withdrawal period:* Sheep (meat) 28 days.

Not for use in sheep producing milk for human consumption.

### 13. SPECIAL STORAGE PRECAUTIONS

**Pharmaceutical Precautions:** Do not store above 25°C. Protect from direct sunlight. Protect from frost. Store in tightly closed original container. Shake container well before use.

### 14. SPECIAL WARNINGS

*Operator Warnings:* When using do not eat, drink or smoke. Wash splashes from eyes and skin immediately. If irritation persists, consult your doctor.

Take off any contaminated clothing immediately. Wash hands and exposed skin before meals and after work.

Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people.

If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using the product, or sore mouth and fever occur shortly afterwards, then medical advice should be sought immediately.

**General Precautions:** Levitape can be given to pregnant and lactating sheep, (provided the milk is not to be used for human consumption), unweaned lambs, and debilitated stock (in the absence of inter-current disease). Due regard must always be given to the physical condition of animals undergoing treatment, particularly those in advanced pregnancy and/or under stress from adverse weather conditions, poor nutrition, penning, handling etc.

Veterinary advice should be sought:

- a) on appropriate dosage programmes and stock management to achieve adequate parasite control and to reduce the likelihood of anthelmintic resistance developing;
- b) if the product does not achieve the desired clinical effect, since other diseases, nutritional imbalances or anthelmintic resistance may be involved.

**Further Information:**

Following the treatment of lungworm infections with Levitape, sheep may sometimes cough for 15 to 30 minutes after treatment.

Chemical group of anthelmintic: 2-LV

**15. EXPIRY DATE**

Exp:

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

**Protection of the Environment:** Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

**17. DATE ON WHICH THE LABEL WAS LAST APPROVED**

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

For animal treatment only.

POM-VPS

**POM-VPS** products may only be prescribed in accordance with a prescription from a Registered Qualified Person (RQP) as follows: (i) a registered veterinary surgeon; (ii) a registered pharmacist; (iii) a registered suitably qualified person (SQP).

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

Keep out of reach and sight of children.

**20. MARKETING AUTHORISATION NUMBER(S)**

Vm 08327/4248

**21. MANUFACTURER’S BATCH NUMBER**

Bn:

**22. OTHER INFORMATION**

Yellow drench.

To be supplied only on veterinary prescription.

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves upwards to the right.

Approved 29 November 2018