SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Levitape Oral Suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance(s)	**mg**
Levamisole……	31.8
(as levamisole hydrochloride…….	37.5)
Praziquantel…….	18.8

Excipients	
Formaldehyde solution……...	2.0
Potassium sorbate……..	1.8

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension.
A white aqueous suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

Levitape is a broad spectrum anthelmintic for use in the treatment and control of nematode and cestode infections in sheep. It is highly effective against mature and developing immature forms of nematodes, including lungworms and against adult forms of tapeworm in sheep. 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

4.3 Contraindications

Do not use in animals 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.

4.4 Special warnings for each target species

At normal levamisole dose levels, sheep rarely show side-effects.
The praziquantel component of Levitape poses no hazard to sheep at normal dose rates.
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 bodyweight, misadministration of the product, or lack of calibration of the dosing device (if any)

Suspected cases of clinical 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*, *Cooperia* and *Trichostrongylus* species in sheep in a number of countries including the EU. There are reports of resistance in *Haemonchus* in sheep outside 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.

4.5 Special precautions for use

i. Special precautions for use in animals

Assess weight as accurately as possible before calculating dosage to avoid underdosing.
Levitape can be given to 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.
Do not exceed recommended dose rates.
Intensive use or misuse of any anthelmintic can give rise to resistance.

ii. Special precautions for the person administering the veterinary medicinal product to animals

When using do not eat, drink or smoke. Wash splashes from eyes and skin immediately. If irritation persists consult your doctor. Take off immediately any contaminated clothing. 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 or fever shortly afterwards, then medical advice should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

At normal levamisole dose levels, sheep rarely show side-effects.
The praziquantel component of Levitape poses no hazard to sheep at normal dose rates.

4.7 Use during pregnancy, lactation or lay

Levitape can be given to pregnant and lactating sheep and unweaned lambs.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer at the same time as a product containing nicotine-like compounds.
Animals must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.
See also 4.3 Contra-indications.

4.9 Amounts to be administered and administration route

Shake container well before use. Using suitably calibrated drenching equipment, administer orally.
Sheep: 7.5 mg/kg levamisole hydrochloride and 3.75 mg/kg praziquantel given orally, equivalent to 1 mL per 5 kg bodyweight.
For example:

Bodyweight	Dose
up to 10kg	2ml
10-15kg	3ml
16-20kg	4ml
21-25kg	5ml
26-30kg	6ml

Above 31kg add 1ml per each 5kg.

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

Do not mix with other products.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Any effect of over-dosage will be due to the levamisole component of the product and symptoms are therefore those of levamisole over-dosage. They are transient and include head shaking, salivation, lachrymation, slight muscle tremors and mild excitability.
There are no specific antidotes for levamisole poisoning.
Praziquantel has a wide margin of safety, and symptoms of poisoning have not been described for sheep.

4.11 Withdrawal periods

Sheep (meat): 28 days
Milk from treated sheep must not be used for human consumption.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC vet code: QP52AE51

Levamisole stimulates both parasympathetic and sympathetic ganglia in parasitic worms, causing a rapid, reversible paralysis which allows them to be expelled from the gut by normal peristaltic action.

Praziquantel causes an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. Praziquantel appears to produce its antiparasitic effects through modulation of the permeability of cell membranes. However, the mechanism of action of praziquantel at a molecular level has not yet been adequately defined. There

are also secondary effects including depolarisation of the schistosome tegument, inhibition of glucose uptake and a decrease in glycogen content.

5.2 Pharmacokinetic particulars

Levamisole is rapidly absorbed from the gastrointestinal tract. In sheep, cattle, pigs and dogs peak levamisole blood levels occur and decrease rapidly. Residues of the drug are higher and more persistent in liver than in kidney or muscle tissue.

After oral administration praziquantel is quantitatively and rapidly absorbed from the gastrointestinal tract. Only a small portion of unchanged drug reaches the general blood circulation when the drug is administered orally. Non-metabolised praziquantel shows only very low maximum serum concentrations owing to an intense first pass effect in the liver. Residues tend to be localised in the excretory organs - liver and kidneys. ^{14}C-praziquantel is hardly taken up at all by the foetus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde solution
Potassium sorbate
Citric acid anhydrous
Macrogol 6000
Polyoxyl 40 Stearate
Propylene glycol
Colloidal anhydrous silica
Xanthan Gum
Water, purified

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

6.4 Special precautions for storage

Do not store above 25^{O}C.
Protect from direct sunlight. Protect from frost.
Store in original container, tightly closed.
Shake container well before use.

6.5 Nature and composition of immediate packaging

1, 2.5 and 5 litre white high density polyethylene jerry can with white, high density polyethylene cap (screw fit).

1, 2.5 and 5 litre white high density polyethylene backpack with white, high density polyethylene cone seal cap (screw fit)

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4248

9. DATE OF FIRST AUTHORISATION

12 April 2002

10. DATE OF REVISION OF THE TEXT

November 2018

Approved 29 November 2018