SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tectomec 0.8 mg/ml Oral Solution Drench for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance
Ivermectin 0.8 mg

Excipient
Benzyl Alcohol 0.03 ml

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution.
Pale yellow clear liquid

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

The treatment and control of gastrointestinal nematodes, and lungworms and nasal bots of sheep.

Gastrointestinal worms (adult and immature):
Haemonchus contortus, Ostertagia circumcincta, Trichostrongylus spp, *Cooperia* spp, *Nematodirus* spp including *N. battus, Strongyloides papillosus*, *Oesophagostomum* spp, and adult *Chabertia ovina*.

Inhibited larval stages and benzimidazole-resistant strains of *H. contortus* and *Ostertagia circumcincta* also controlled.

Lungworms (adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

4.3 Contraindications

The product has been formulated specifically for use in sheep. It should not be used in other species, as adverse reactions, including fatalities in dogs, may occur.

The product is not for intravenous or intramuscular use.

4.4 Special Warnings for Each Target Species

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 ivermectin (an avermectin) has been reported in *Teladorsagia* in sheep and goats within the EU and it is common 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 nematode 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

None

ii. Special precautions to be taken by the person administering the product to the animals

Do not smoke, drink or eat while handling the product.
Wash hands after use.
Avoid contact with skin and eyes. In cases of accidental eye or skin contact, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

4.6 Adverse reactions (frequency and seriousness)

Some animals may cough slightly immediately after treatment. This is a temporary occurrence and is of no clinical consequence.

4.7 Use during pregnancy, lactation or lay

The product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption.

4.8 Interactions with other medicinal products and other forms of interaction

None known.

4.9 Amount to be administered and administration route

Ivermectin should be administered at a dosage rate of 200 μg per kg bodyweight (2.5 ml per 10 kg bodyweight). It should be administered orally. It is recommended that a suitably calibrated dosing gun is used to allow accurate dosing especially in young animals.

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)

No antidote has been identified, however symptomatic treatment may be beneficial.

4.11 Withdrawal period

Sheep (Meat): 14 days

Do not use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Avermectins

ATCvet Code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin is a 22,23-dihydro derivative of an avermectin (which is a fermentation product produced by *Streptomyces avermitilis*) and consists of 2 homologues: B1a and B1b. It is a highly effective parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.

Avermectins interact with glutamate-gated chloride ion channels, to increase membrane permeability to chloride ions, causing irreversible neuromuscular blockade in nematodes, followed by paralysis and death.

5.2 Pharmacokinetic properties

Premadex 0.8 mg/ml was administered orally to sheep at a dose of 200 µg/kg. Maximum plasma concentration was 5.99 µg/ml at 16.2 hours after administration and the elimination half-life was approximately 25 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Polysorbate 80
Dimethylacetamide
Sodium Phosphate Dihydrate
Sodium Acid Phosphate Dihydrate
Water Purified

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Do not store above 25°C.

Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

1.0L, 2.5L and 5.0L and 2 x 5.0L white high density polyethylene jerrycans and back-packs with white polypropylene caps (screw-fit) surmounting board faced aluminium foil induction seal.

Not all pack sizes may be marketed.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used container. 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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

02000/4198

9. DATE OF FIRST AUTHORISATION

18 January 2002

10. DATE OF REVISION OF THE TEXT

April 2018

Approved: 13 April 2018