

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Paramectin Drench 0.8 mg/ml Oral Solution

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**Active Substance:**

Ivermectin 0.8 mg/ml

**Excipients:**

Benzyl alcohol 30 ml/ml

For the full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Oral solution

A pale yellow clear liquid

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Sheep

#### **4.2 Indications for use, specifying the target species**

Treatment and control of gastrointestinal nematodes, 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* are 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 severe adverse reactions, including fatalities in dogs, may occur.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

The product is not for intravenous or intramuscular use.

Do not use in sheep producing milk for human consumption.

#### **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 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

None

##### ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact with skin and eyes.

In case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

Do not smoke, drink or eat while handling the product.

Wash hands after use.

#### **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 Interaction with other medicinal products and other forms of interaction**

None known

#### **4.9 Amount(s) 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, body weight 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**

The product has demonstrated a wide safety margin at the recommended dose rate. No antidote has been identified however symptomatic treatment may be beneficial.

#### **4.11 Withdrawal period(s)**

Meat and offal: 14 days

Do not use in sheep producing milk for human consumption.

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic Group:** Endectocide

**ATC Vet Code:** QP54 AA 01

#### **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 selectively and with high affinity with glutamate-gated chloride ion channels, which only occur in invertebrate nerve and muscle cells. This increases membrane permeability to chloride ions, causing irreversible neuromuscular blockades in nematodes, followed by paralysis and death. The macrocyclic lactones have a low affinity for other mammalian ligand gated chloride channels and they do not readily cross the blood brain barrier.

## **5.2 Pharmacokinetic particulars**

After administration orally to sheep at a dose of 200 µg/kg, maximum plasma concentration of ivermectin 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 Major 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.  
Keep container in outer carton

### **6.5 Nature and composition of immediate packaging**

Supplied in 1.0L, 2.5L, 5.0L and 2 x 5.0L volumes, presented in high density polyethylene Jerry Cans or high density polyethylene back-packs with polypropylene closures.

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**

**EXTREMELY DANGEROUS** to fish and aquatic life do not contaminate ponds, waterways or ditches with the product or unused 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**

Vm 02000/4263

**9. DATE OF FIRST AUTHORISATION**

08 November 2006

**10. DATE OF REVISION OF THE TEXT**

July 2018

**Further information:**

Ivermectin belongs to the avermectin (3-AV) class of anthelmintic compounds, chemical group of anthelmintic 3-AV.

Approved: 27 July 2018

