

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Primectin 0.5% w/v Pour-On Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### **Active Ingredient**

Ivermectin 0.5 % w/v

### **Excipients**

Isopropyl alcohol to 100.0 % v/v

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Pour-on solution.  
A clear blue solution.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Beef and non-lactating dairy cattle.

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

Primectin Pour On is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eyeworms, warbles, mites and lice.

#### **Gastrointestinal roundworms (adults and fourth stage larvae):**

*Ostertagia ostertagi* (including inhibited *O. ostertagi*), *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp. *Oesophagostomum radiatum*, *Strongyloides papillosus* (adult), *Trichuris* spp (adult). Occasionally variable activity may be observed against *H. placei* (L4), *Cooperia* spp, *T. axei* and *T. colubriformis*.

#### **Lungworms (adult and fourth stage larvae):**

*Dictyocaulus viviparus*

#### **Eyeworms (adult):**

*Thelazia* spp

#### **Warbles (parasitic stages):**

*Hypoderma bovis*, *Hypoderma lineatum*

#### **Sucking Lice:**

*Linognathus vituli*, *Haematopinus eurytenuis*

#### **Biting Lice:**

*Damalinea bovis*

#### **Mange mites:**

*Chorioptes bovis*, *Sarcoptes scabiei* var *bovis*

### 4.3 Contraindications

Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption. Do not use in pregnant heifers within 60 days prior to calving.

### 4.4 Special warnings for each target species

Assess bodyweight as accurately as possible before calculating the dosage.

#### 4.5 Special precautions for use

##### Special precautions for use in animals

To avoid secondary reactions due to death of *Hypoderma* larvae in the oesophagus or in the spine it is recommended to administer the product at the end of the period of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.

Frequent and repeated use may lead to the development of resistance. It is important that the correct dose is given in order to minimise the risk of resistance development.

Do not treat cattle when their hair or hide is wet. Do not treat cattle if rain is expected, as rain within 2 hours of treatment may reduce efficacy. Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.

Ivermectin is not tolerated well in all non target species (cases of intolerance with fatal outcome are reported in dogs – especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

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

Highly flammable - keep away from heat, spark, open flame or other sources of ignition.

Primectin Pour On may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protection clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eye immediately with water and get medical attention.

Do not smoke or eat while handling the product. Wash hands after use. Use only in well ventilated areas or outdoors.

#### 4.6 Adverse reactions (frequency and seriousness)

None

#### 4.7 Use during pregnancy, lactation or lay

Primectin Pour On for cattle can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

Do not use in cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

#### 4.8 Interaction with other medicinal products and other forms of interactions

No data available.

#### 4.9 Amounts to be administered and administration route

Primectin should be administered topically at 500 microgram ivermectin per kg bodyweight (1 ml per 10 kg bodyweight). The formulation should be applied along the midline of the back in a narrow strip between the withers and the tailhead. It is recommended that calves which are set-stocked in their first season of grazing should be treated 3, 8 and 13 weeks after turnout, for optimal benefit from the persistent effect of ivermectin. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season, provided they are set-stocked. All calves should be included in the program, and no untreated cattle should be added to the pasture. Treated animals should be monitored according to good husbandry practices always.

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

In case of overdose a symptomatic treatment should be given. The symptoms of overdose can be trembling, convulsions and coma.

#### 4.11 Withdrawal period(s)

Meat and offal: 28 days

Not permitted for use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant heifers within 60 days prior to calving.

### 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QP54 AA01

Therapeutic group: Endectocide

Ivermectin is a mixture of two partially modified compounds of abamectin belonging to the avermectin family, which are a macrocyclic lactone group of endectocides. Abamectin is a mixture of two fermentation products of the soil organism *Streptomyces avermitilis*.

### 5.1 Pharmacodynamic properties

Ivermectin is a macrocyclic lactone derivative and acts by inhibiting nerve impulses. It binds selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate gated chloride channels. 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 of the recommended dosage to cattle, varying inter-individual ivermectin plasma levels were observed with mean values of  $C_{max}$  and  $t_{max}$  of 11.26 ng/ml and 97h, respectively.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Crodamol CAP  
Triethanolamine  
Patent Blue V Dye  
Isopropyl alcohol

### 6.2 Major incompatibilities

None

### 6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life after first opening the immediate packaging: 1 year.

### 6.4 Special precautions for storage

Store below 30°C.

### 6.5 Nature and composition of immediate packaging

Primectin Pour-On will be supplied in 250ml and 1.0L twin-neck and squeeze-measure high density polyethylene dispensers and 2.5L and 5L low density polyethylene backpacks.

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

Ivermectin is extremely dangerous to fish and aquatic life. Do not contaminate surface water or ditches with the product or used containers. Any unused product or waste material should be disposed of in accordance with national requirements.

**7 MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories (Ireland) Limited  
Rossmore Industrial Estate  
Monaghan  
Ireland

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA22664/078/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 08 December 2000

Date of last renewal: 07 December 2005

**10 DATE OF REVISION OF THE TEXT**

February 2019