

# Wormec

# ورمک سُپر انجکشن

## SUPER

### Injection

### (Ivermectin, Clorsulon)

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

Wormec Super 10 mg/ml / 100 mg/ml Solution for Injection

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

1 ml of solution contains:

- Ivermectin 10mg
- Clorsulon 100mg

#### 3. PHARMACEUTICAL FORM

Solution for injection a clear colorless to pale yellow colored non-aqueous solution.

#### 4. CLINICAL PARTICULARS

##### 4.1 Target Species

Cattle, Camel, Sheep & Goat

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

For the treatment of mixed infestation of adult liver fluke and gastro-intestinal roundworms, lungworms, eye worms, and/or mites and lice of beef and non-lactating dairy cattle.

##### Gastrointestinal Roundworms (adult and fourth-stage larvae):

- *Ostertagia ostertagi* (including inhibited larval stages)
- *O. lyrata* *Haemonchus placei*
- *Trichostrongylus axei*
- *T. colubriformis*
- *Cooperia Oncophora*
- *C. punctata*
- *C. pectinata*
- *Bunostomum phlebotomum*
- *Oesophagostomum radiatum*
- *Strongyloides papillosus* (adult)
- *Nematodirus helvetianus* (adult)
- *Nematodirus spathiger* (adult)
- *Trichuris* spp. (adult)

##### Lungworm (adult and fourth-stage larvae):

- *Dictyocaulus viviparus*

##### LIVER FLUKE (ADULT):

- *Fasciola hepatica*

##### EYE WORMS (ADULT):

- *Thelazia* spp.

##### Warbles (parasitic stages):

- *Hypoderma bovis*
- *H. lineatum*

##### MANGE MITES:

- *Psoroptes bovis*
- *Sarcoptes scabiei* var. *bovis*

##### Sucking Lice:

- *Linognathus vituli*
- *Haematopinus euryternus*
- *Solenopotes Capillatus*

The product may also be used as an aid in the treatment of biting lice (*Damalnia bovis*) and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

#### 4.3 Contraindications:

Do not use this product intravenously or intramuscularly. This product is a low volume product authorized for use in cattle. It must not be used in other species as severe adverse reactions, including fatalities in dogs, may occur, especially Collies, Old English Sheepdogs and related breeds or crosses. Do not use in animals with a known sensitivity to the active ingredient or to any of the excipients.

#### 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 bodyweight, 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 macrocyclic lactones (which includes Ivermectin) has been reported in *Ostertagia ostertagi* and *Cooperia* spp. in cattle within 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

This product does not contain any antimicrobial preservative. Swab septum before removing each dose. To avoid secondary reactions due to the death of Hypo-derma larvae in the esophagus or the spine, it is recommended to administer the product at the end of the period of fly activity and before the larvae reach their resting sites: seek professional advice on the correct timing of treatment.

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

Do not eat, drink or smoke whilst handling the product. Wash hands after use. Direct contact with the skin should be avoided. Wear gloves and glasses when handling the veterinary medicinal product. Take care to avoid self-injection: the product may cause local irritation and/or pain at the site of injection. In case of accidental self-injection, seek medical advice and show the label to the doctor.

##### iii) Other precautions

The product is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore repeated treatment of animals on a pasture with an Ivermectin-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

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

Transient discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the site of injection has been observed. These reactions disappeared without treatment.

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

Can be used in pregnancy and lactation.  
Can be used in breeding animals.

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

Dosage and duration of treatment

For subcutaneous use. A single dose of 1ml of the product per 50kg bodyweight, i.e. 200µg Ivermectin and 2mg Clorsulon per kg bodyweight.

##### Method of administration

The product should be administered only by subcutaneous injection under the loose skin in front of or behind the shoulder. Divide doses greater than 10ml between two injection sites. A sterile 17 gauge (15-20 mm) needle is recommended.

Different injection sites should be used for other parenteral products administered concurrently. When using the 500 ml pack size use only automatic syringe equipment. For the 50 ml pack size, use of a multidose syringe is recommended.

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person.

To ensure a correct dosage, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, to avoid under- or overdosing, they should be grouped according to their bodyweight and dosed accordingly.

When the temperature of the product is below 5°C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15°C will greatly increase the ease with which the product can be injected.

**4.9 Overdose (symptoms, emergency procedures, antidotes),**  
if necessary A dose of 25 ml per 50kg bodyweight (25 times the recommended dose level) may result in injection site lesions, including tissue necrosis, edema, fibrosis and inflammation. No other drug-related reactions have been observed.

**4.10 Withdrawal period(s)**  
Meat and offal: 66 days Milk: Do not use in cattle producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

## **5 PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic Group: Endectocides

### **5.1 Pharmacodynamic properties**

Ivermectin is a member of the macrocyclic lactone class of endectocides, which have a unique mode of action. It has broad and potent antiparasitic activity. 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 parasite. Compounds of this class may also interact with other ligandgated chloride channels, such as those gated by the neurotransmitter gammaaminobutyric 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. Clorsulon is a sulphonamide and is rapidly absorbed in the blood stream. It is bound to the erythrocytes and plasma which are ingested by the fluke. Clorsulon inhibits the glycolytic enzymes in the fluke and deprives it of its main source of metabolic energy.

### **5.2 Pharmacokinetic properties**

After subcutaneous administration of the product at the recommended dose, 2 mg Clorsulon and 0.2 mg Ivermectin per kg bodyweight, the plasma profile demonstrated a slow absorption of Ivermectin with mean maximum plasma levels of 65.8 ng/ml reached at 36 hours. In contrast, Clorsulon appeared rapidly absorbed with mean maximum plasma levels of 2.58 µg/ml reached at 6 hours. The terminal half-life for the two active ingredients were determined as follows: Ivermectin approximately 3.79 days and Clorsulon approximately 3.58days

### **5.3 Environmental properties**

Like other macrocyclic lactones, Ivermectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of Ivermectin may take place over a period of several weeks. Faeces containing Ivermectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.2 Incompatibilities**

In the absence of compatibilities studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### **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: Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

### **6.4 Special Precautions for storage**

Store below 30°C in a cool, dry place.  
Protect from light & Heat.  
Keep out of reach of children

### **6.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products.**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container.

## **7 How Supplies:**

Ambler Glass container with bromobutyl rubber stopper and aluminium cap.

MANUFACTURED BY:



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