Wormec Super Injection

(Ivermectin & Clorsulon)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wormec-Super Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
1ml contains:
Ivermectin 10mg
Clorsulon 100mg

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of mixed trematode and nematode or arthropod infestations of the following parasites:

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
Oesophagostamum radiatum
Strongyloides papillosus (adult)
N. spathiger (adult)
N. helvetianus (adult)

Lungworms (adult and fourth-stage larvae)
Dictyocaulus viviparous

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 eurysternus Solenopotes capillatus.*

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

Persistent activity

The product given at the recommended dosage of 1ml/50kg bodyweight controls re- infection with *Haemonchus placei, Cooperia* spp. and *Trichostrongylus axei* acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

4.3 Contraindications

Do not use intramuscularly or intravenously.
This product is a low volume product authorised 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 cases of hypersensitivity to the active substance 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 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 has been reported in Ostertagia ostertagi and Cooperia species in cattle within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of these helminth species 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.

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

Do not smoke or eat whilst handling the product.
Wash hands after use.
Wear gloves and glasses when handling the veterinary medicinal product. Direct contact with the skin should be avoided.
Take care to avoid self-injection: the product may cause local irritation and/or pain at the injection site.

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 repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

4.6 Adverse reactions (frequency and seriousness)

Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site 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 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dosage and duration of treatment

200µg ivermectin and 2mg clorsulon per kg bodyweight corresponding to a single dose of 1ml per 50kg 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 in excess of 10 ml between different injection sites and use different sites to those used for other parenteral medications.

A sterile 17 gauge ½ inch (15-20mm) needle is recommended. Replace with a fresh sterile needle after every 10-12 animals or sooner if the needle becomes soiled.

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.

When using the 500ml pack size use only automatic syringe equipment. For the 50ml 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, body weight 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 over-dosing, they should be grouped according to their bodyweight and dosed accordingly.

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

A dose of 25ml product per 50kg bodyweight (25 times the recommended dose level) may result in an injection site lesion, including tissue necrosis, oedema, fibrosis and inflammation. No other drug-related reactions have been observed.

4.11 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, macrocyclic lactones, avermectins**,** ivermectin - combinations
ATC vet code: QP54AA51

5.1 Pharmacodynamic properties

Ivermectin is a member of the macrocyclic lactone class of endectocides and has 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 hyperpolarisation of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels such as those gated by the neurotransmitter gamma-amino-butyric 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, that 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 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 2mg clorsulon and 0.2mg ivermectin per kg bodyweight, the plasma profile demonstrated a slow, steady absorption of ivermectin which reached a maximum plasma concentration at a median time of 1.50 days. In contrast, clorsulon appeared rapidly absorbed with a maximum plasma concentration at a median time of 0.25 days. The terminal half life for the two active ingredients were determined as follows: Ivermectin approximately 3.79 days and Clorsulon approximately 3.58 days

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

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

6.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use within 28 days, do not store.

6.3 Special precautions for storage

Store below 25°C.
Protect from light and moisture.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.4. Nature and composition of primary conditioning

Cardboard box with glass injection vial (s).
Amber glass vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.
Pack sizes: 10ml, 50ml & 100ml

6.5 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 surface waters 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

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 058993

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 28-08-2009

10. DATE OF REVISION OF THE TEXT

15-07-2024

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.

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