WORMEC DRENCH
(Ivermectin)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

WORMEC DRENCH.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Liter Contains:
Ivermectin …… 0.880gm

3. PHARMACEUTICAL FORM

Oral Solution.

4. CLINICAL INFORMATION

4.1. Target species

Sheep and Goats.

4.2. Indications for use specifying the target species

For the treatment and control of the following parasitic infestations in sheep:
Gastrointestinal nematodes:
o Haemonchus contortus (adults, L3 and L4 including hypobiotic larvae)
o H. placei (adults)
o Teladorsagia (Ostertagia) circumcincta (adults, L3 and L4 including hypobiotic larvae)
o Trichostrongylus axei (adults and L4)
o T. colubriformis (adults, L3 and L4)
o T. vitrinus (adults and L4)
o Cooperia curticei (adults and L4)
o C. oncophora (adults)
o Gaigeria pachyscelis (adults, L3 and L4)
o Nematodirus battus (adults and L4)
o N. filicollis (adults and L4)
o N. spathiger (adults, L3 and L4)
o Strongyloides papillosus (adults, L3 and L4)
o Chabertia ovina (adults, L3 and L4)
o Trichuris ovis (adults)
o Oesophagostomum columbianum (adults, L3 and L4)
o O. venulosum (adults)
 Pulmonary nematodes (lungworms):
o Dictyocaulus filaria (adults, L3 and L4)
 Oestrosis caused by:
o Oestrus ovis (all larval stages)

For the treatment and control of the following parasitic infestations in goats:
 Gastrointestinal nematodes (adults and L4):
o Haemonchus contortus
o Teladorsagia (Ostertagia) circumcincta
o Trichostrongylus colubriformis
o Nematodirus spathiger
o Strongyloides papillosus
o Oesophagostomum columbianum
o Chabertia ovina (adults)
 Pulmonary nematodes (adults):
o Dictyocaulus filarial

4.3. Contraindications

Do not use in cases of known hypersensitivity to the active substance and/or any of the excipients.

4.4. Special warnings for each target species

The following practices should be avoided as they increase the risk of resistance development, which can lead to ineffective therapy:
 Frequent and repeated use of anthelmintics of the same class or over an extended period.
 Underdosing, which may be due to an incorrect estimate of body weight, improper use of the medication, or lack of calibration of the dosing device.
Cases of resistance to macrocyclic lactones (including avermectin, ivermectin) have been reported in Teladorsagia spp. in sheep within the EU. Therefore, the use of this medication should be based on local epidemiological information (at the regional or farm level) regarding the susceptibility of nematodes and recommendations on how to limit further selection for anthelmintic resistance.
If resistance to a specific anthelmintic is suspected in clinical cases, this should be investigated with appropriate tests (e.g., Faecal Egg Count Reduction Test). When results clearly indicate resistance, an anthelmintic from a different pharmacological group or with a different mechanism of action should be administered.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Avermectins are not well tolerated by some animal species for which the product is not authorized. Severe cases of intolerance, resulting in death, have been observed in dogs (especially collies, Old English sheepdogs, similar breeds, and their crosses) and in tortoises.

Special precautions to be taken by the person administering the product to animals:

People with known hypersensitivity to ivermectin should avoid all contact with the product.

Avoid contact with skin and eyes. Wear personal protective equipment, including impermeable gloves, when handling and administering the product.
Since skin absorption can occur, in case of accidental skin contact, wash the affected area immediately with soap and water.
If accidental eye exposure occurs, wash eyes immediately with water.
Do not smoke or eat while handling the product.
Wash hands after use.

Special precautions for environmental protection:

It does not proceed.

4.6. Adverse reactions (frequency and seriousness)

Some animals may cough immediately after administration. This response is temporary and has no consequences.

4.7. Use during pregnancy and lactation or lay

No contraindications have been described for use in pregnant sheep. No information is available for goats.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

None known.

4.9. Dosage and administration route

Route: Oral.
Dosage: 0.2 mg of ivermectin/kg body weight (equivalent to 2.5 ml/10 kg body weight). To ensure correct dosing, body weight should be determined as accurately as possible, and the accuracy of the dosing device should be checked. If animals are to be treated collectively, they should be grouped by body weight, and dosing should be based on those weights to avoid both underdosing and overdosing.

The timing or schedule of treatment should be based on epidemiological factors and be personalized for each farm. The treatment program should be established by a veterinarian.

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

The safety margin is wide. If clinical signs of an overdose appear (ataxia, depression), institute symptomatic treatment.

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Medication administered under the control or supervision of the veterinarian

4.12. Withdrawal period:

Sheep:
Meat: 6 days.
Goats:
Meat: 8 days.
Milk: Use is not authorized in animals whose milk is intended for human consumption. Do not use in pregnant animals whose milk will be used for human consumption within 60 days of the expected date of parturition.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides. Macrocyclic lactones. Avermectins.
 ATCvet code: **QP54AA01**

5.1. Pharmacodynamics properties

Ivermectin is an endectocide belonging to the macrocyclic lactone class, which has a unique mode of action. It selectively and with high affinity binds to glutamate-gated chloride ion channels found in the nerve and muscle cells of invertebrates. This leads to an increase in the cell membrane's permeability to chloride ions, causing hyperpolarization of the nerve or muscle cell, which results in paralysis and death of the parasite. Compounds in this class can also interact with other mediator-gated chloride ion channels, such as gamma-aminobutyric acid (GABA).
The safety margin of these compounds in mammals is attributed to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mediator-gated chloride channels in mammals, and they do not easily cross the blood-brain barrier.

5.2. Pharmacokinetic information

After oral administration of a 0.3 mg ivermectin/kg body weight dose, a maximum plasma concentration of 12 to 34 ng/ml is reached at 6 hours. This concentration gradually decreases to values between 2 and 7 ng/ml two days after administration. The highest levels of ivermectin are found in fatty tissue and the liver. Excretion occurs mainly in the feces.

6. PHARMACEUTICAL INFORMATION

6.1 Excipients

Benzyl alcohol (E-519)
Propylene glycol
Polysorbate 80
Sodium hydrogen phosphate dodecahydrate
Sodium dihydrogen phosphate dihydrate
Purified water

6.2 Incompatibilities

In the absence of compatibility 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 container: use within 28 days, do not store.

6.4. Special precautions for storage

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

6.5. Nature and composition of primary conditioning

The product is available in various pack sizes:

- **For 100ml:** PET bottles with tightly sealed caps.
- **For 250mL & 500mL:** HDPE bottles with induction-sealed caps.
- **For 1L:** HDPE can with induction-sealed caps.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

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.: 035060

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 13-12-2004

10. DATE OF REVISION OF THE TEXT

17-02-2025