NAWAMAX DRENCH SOLUTION
(Oxfendazole)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NAWAMAX DRENCH SOLUTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:
Oxfendazole …….. 2.265g

3. PHARMACEUTICAL FORM

Oral Suspension.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, sheep and goats.

4.2. Indications for use specifying the target species

Treatment of infestations by the following parasites:
In cattle:

- Gastrointestinal nematodes (adults and L4 larvae): Ostertagia ostertagi (including inhibited larvae) Trichostrongylus spp Cooperia onchophora Nematodirus helvetianus Bunostomum phlebotomum Strongyloides papillosus Radiated Oesophagostomum
- Lungworms (adults and L4 larvae): Dictyocaulus viviparus

In sheep and goats:
Gastrointestinal nematodes (adults and L4 larvae): Trichostrongylus spp Haemonchus contortus (including inhibited larvae) The cottage cooperative Nematodirus spp. Bunostomum trigonocephalus Strongyloides papillosus Oesophagostomum venulosum Chabertia ovina

- Lungworms (adults and L4 larvae): Dictyocaulus filaria
- Cestodes: Moniezia spp

4.3. Contraindications

Do not use in case of hypersensitivity to the active substance. Do not use if resistance to benzimidazoles is suspected

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Resistance to all benzimidazoles can develop with frequent and repeated use of an antiparasitic of this class.

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

Avoid direct contact with skin. Wash hands thoroughly after use. Personal protective equipment, including waterproof gloves, must be worn when handling the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the doctor.

Special precautions for environmental protection

Not applicable.

4.6. Adverse reactions (frequency and seriousness)

Cattle, sheep and goats:
Not reported.
Reporting adverse reactions is important. Reporting allows for continuous monitoring of the safety of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, either to the marketing authorization holder or their local representative, or to the national competent authority via the national reporting system. See the package leaflet for contact details.

4.7. Use during pregnancy and lactation or lay

Gestation:
In laboratory animals, oxfendazole, like a number of other benzimidazoles, causes a reduction in the functions of the male reproductive system and has embryo toxic and teratogenic properties.
In sheep, oxfendazole is embryo toxic and teratogenic at 4 times the recommended dose when administered during the first third of gestation.
In cattle, eight administrations at 4-day intervals at a dose of 13.6 mg/kg between the 11th and 39th days of gestation did not cause any effect on the embryo.

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

None known.

4.9. Dosage and administration route

Oral route.

In cattle: 4.5 mg of oxfendazole per kg of body weight, or 20 mL of suspension per 100 kg of body weight in a single administration.

In sheep: 5 mg of oxfendazole per kg of body weight, or 2.2 mL of the suspension per 10 kg of body weight in a single administration.

In goats: 10 mg of oxfendazole per kg of body weight, or 4.4 mL of the suspension per 10 kg of body weight in a single administration.

To ensure proper dosage, body weight should be determined as accurately as possible.

Shake the suspension well before use to ensure good homogeneity of the veterinary medicinal product.

The use of a clean and properly calibrated metering gun is recommended.

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

Not known.

4.11 Specific restrictions on use and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products to reduce the risk of development of resistance

Not applicable.

4.12. Withdrawal period:

Bovines:
- Meat and offal: 15 days.
- Milk 7 days.

Sheep:
- Meat and offal: 14 days.
- Milk 8 days.

Goats:
- Meat and offal: 28 days.
- Milk 14 days.

5. PHARMACOLOGICAL PROPERTIES

ATC-vet code: **QP52AC02.**

5.1. Pharmacodynamics properties

Oxfendazole belongs to the class of benzimidazoles, molecules with antimitotic properties. This activity is linked to their ability to bind to β-tubulin, thus preventing microtubule polymerization. Destruction of the microtubule network often leads to cell disaggregation and death.
Oxfendazole appears to preferentially concentrate in the intestinal cells of parasites to exert its main toxic effects there. The lack of similar effects in host cells is likely due to different binding mechanisms.
Oxfendazole is the sulfoxide metabolite of fenbendazole. Both molecules are known for their anthelminthic activity and for having reversible metabolism.
Oxfendazole exhibits activity against gastrointestinal nematodes (including encysted larvae of Haemonchus and Ostertagia spp), lungworms, and cestodes.

5.2 Pharmacokinetic information

After oral administration, reduction of oxfendazole to fenbendazole occurs in the ruminal fluid, while oxidation of fenbendazole to oxfendazole is carried out by hepatic microsomal enzymes.

Metabolism is extensive after oral administration, and the primary metabolites appear to be relatively rapidly eliminated via urine and biliary tracts. The metabolites are generally more water-soluble than the parent molecule and are therefore more readily excreted.

6. PHARMACEUTICAL INFORMATION

6.1 List of Excipients:

Anhydrous citric acid
Sodium hydroxide
Macrogol 6000
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.
Protect from light and moisture.
Shake well before use.
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

Pack sizes:
For 100ml: HDPE bottle is closed with PP Cap with induction sealed
For 500ml & 1 Liter: HDPE Can is closed with PP Cap with induction sealed

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

Waste materials derived from the use of such products
Medicinal products should not be disposed of via wastewater or household waste.
Use return systems for unused veterinary medicinal products or waste materials derived from such products, in accordance with local requirements and national collection systems applicable to the veterinary medicinal product concerned.
Treated animals should be kept in shelters throughout the treatment period and their droppings should be collected and NOT used for soil fertilization.

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.: 021307

9. DATE OF FIRST AUTHORISATION

Date of Reg: 11-05-1998

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.

136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.