# Dorantil
# Solution for Injection
(Doramectin)

**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**
Dorantil Solution for Injection

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**
Each mL Contains:
Doramectin …… 10mg

Quality composition of auxiliary materials and other components

Ethyl oleate
Sesame oil
Butylhydroxyanisole
Clear, colorless or pale yellow solution.

**3. CLINICAL DATA**
**3.1 Target animal species(s)**
Cattle, sheep, goats.

**3.2 Therapeutic indications by target animal species**
For the treatment of the ecto- and endoparasitises listed below in cattle, sheep and goats.
**Cattle:** For the treatment and prevention of parasitosis caused by the listed gastrointestinal worms, lungworms, eyeworms, hookworms, blood-sucking lice and mites.
**Gastrointestinal worms** (adults and fourth-stage larvae L4): Ostertagia ostertagi (adult, L4, including hypobiotic larvae), Ostertagia lyrata (adult), Haemonchus placei (adult, L4), Trichostrongylus axei (adult, L4), Trichostrongylus colubriformis (adult, L4), Cooperia oncophora (adult, L4), Cooperia pectinata (adult), Cooperia punctata (adult, L4), Cooperia surnabada (syn.: mcmasteri) (adult, L4), Nematodirus spathiger
(adult), Bunostomum phlebotomum (adult) Strongyloides papillosus (adult), Oesophagostomum radiatum (adult, L4), Trichuris spp. (adult**)**
**Lungworm** (adult and fourth stage larva): Dictyocaulus viviparus.
**Eyeworm:** (adult) Thelazia spp.
**Hookworm larvae** (parasitic stages): Hypoderma bovis, Hypoderma lineatum.
**Blood-sucking lice:** Haematopinus eurysternus, Linognathus vituli, Solenopotes capillatus, Scabies: Psoroptes bovis, Sarcoptes scabei.
The preparation helps in the protection against the intestinal worm Nematodirus helvetianus, the hair louse Damalinia bovis, and the roundworm Chorioptes bovis.

According to the pharmacokinetic studies of the preparation, the duration of its protective effect against infection and re-infection with the listed parasites is a maximum of:
22 days Bunostomum phlebotomum
21 nap Cooperia oncophora
35 nap Dictyocaulus viviparus
28 days Haemonchus placei (adult only)
28 nap Linognathus calf,

35 nap Ostertagia ostertagi
21 nap Oesophagostomus radiate
28 nap Trichostrongylus axei 42 nap Psoroptes spp.

**Sheep & Goats:** For the treatment and prevention of parasitosis caused by gastro-intestinal worms, lungworms, and roundworms.

**Gastrointestinal worms:** Chabertina ovina (adults), Cooperia curticei (only L4), Cooperia oncophora (adult, L4), Gaigeria pachyscelis (adult, L4), Haemonchus contortus (adult, L4), Nematodirus spp. (L4)*, Oesophagostomum columbianum (adult, L4), Ostertagia (Teladorsagia) circumcincta (adult, L4 also affects hypobiotic larvae and benzimidazole-resistant strains), Strongyloides papillosus (adult, L4), Trichostrongylus axei (adult, L4) , Trichostrongylus colubriformis (adult, L4), Trichostrongylus vitrines (adult L4), Trichuris spp. (adult only).
***Lungworm:*** Dictyocaulus filaria (adult only).
***Oestrus ovis*** (L1, L2, L3).
***Rühatka:*** Psoroptes ovis*.

In order to achieve effective treatment, an increased dose of 300 µg doramectin/kg body weight is required for Psoroptes ovis mites and Nematodirus battus adults and L4.

**3.3 Contraindications**
Apart from the target animal species, other species cannot be treated with the preparation.
It cannot be used on dogs, as serious, unwanted effects may occur, collie breeds are especially sensitive to doramectin.
It cannot be used in case of hypersensitivity to the active substance or any excipient.

**3.4 Special warnings**
In cattle, in order to avoid the possible death of Hypoderma larvae in the esophagus or the spinal column, it is recommended to use the product at the end of the active period of the flies, before the final settlement of the larvae.

Care must be taken to prevent the following practices, because they increase the risk of developing resistance and ultimately lead to the ineffectiveness of the treatment: - too frequent and repeated use of anthelmintics belonging to the same group over a long period of time, which can be caused by underestimation of body weight, inappropriate drug administration or failure to calibrate the dosing device (if available).
In the case of suspicion of resistance to anthelmintics, further tests must be carried out with appropriate tests (e.g. a decrease in the number of eggs discharged in the faeces). If the results of the tests specifically indicate resistance to a certain anthelmintic, a preparation belonging to another pharmacological group with a different mechanism of action should be used.

Resistance to avermectins in sheep has been reported in Teladorsagia and Haemonchus species in the EU.

Therefore, this product should be used based on local (regional, colony) epidemiological information on the sensitivity of nematodes and recommendations to prevent the further spread of resistance to anthelmintics.

**3.5 Special precautions for use**
Special precautions for safe use in target species: Not applicable.
Special precautions for the person handling the animals:
Before using the product, you must read the instructions for use. It is forbidden to smoke, eat or drink while using the product. Hand washing is required after use. Care must be taken when

using the product to avoid accidental self-injection. In the case of self-injection, a doctor must be consulted immediately, presenting the instructions for use or the label of the product.
Special precautions for the protection of the environment:
Doramectin is particularly toxic to dung-forming organisms and aquatic life and can accumulate in sediments. By avoiding the frequent and repeated use of doramectin (and anthelmintics belonging to the same group) in cattle and sheep, the risk to the aquatic ecosystem and manure can be reduced.

The risk to the aquatic ecosystem can be further reduced by keeping treated cattle away from live waters for 2-5 weeks after treatment.

**3.6 Side effects**
Cattle, sheep & goats.

Not known.

It is important to report side effects. This enables continuous monitoring of the safety of the veterinary medicinal product. If possible, the reports should be sent via the veterinarian to the marketing authorization holder.

**3.7 Use during pregnancy, lactation or egg laying**
Pregnancy and lactation:
Can be used in pregnant cows, sheep and goat. The preparation can be given to breeding and lactating cows, as well as breeding males.

See 3.12. section.

**3.8 Drug interaction and other interactions**
They are not known.

**3.9 Method of application and dosage**
Cattle: subcutaneous application.
Sheep & goat: Intramuscular use.

Cattle: 1 ml (10 mg doramectin) / 50 kilograms of body weight, which corresponds to a dose of 200 µg / kg body weight. The product should be injected under the thinner skin of the neck or shoulder area with a dry, sterile 15 mm long, 16-18 needle.

With a dose of 200 µg doramectin/kg body weight (1 ml/50 kg body weight) subcutaneously according to the table below:

| **Body weight (kg)** | **Solid (ml)** | **Body weight (kg)** | **Solid (ml)** |
|---|---|---|---|
| Up to 50 kg | 1 | 301-350 | 7 |
| 51-100 | 2 | 351-400 | 8 |
| 101-150 | 3 | 401-450 | 9 |
| 151-200 | 4 | 451-500 | 10 |
| 201-250 | 5 | 501-550 | 11 |
| 251-300 | 6 | 551-600 | 12 |

It is recommended to treat cattle before turning them out to pasture and again after 8 weeks. Untreated cattle should not be allowed on pasture used by treated animals.

***Sheep & goats:*** 1 ml (10 mg doramectin) / 50 kilograms of body weight, which corresponds to a dose of 200 µg / kg body weight. The preparation must be administered intramuscularly in the neck area, with a dry, sterile 25 mm long, 16-18 needle.

The dosage against Psoroptes ovis and Nematodirus battus infection is 1 ml (10 mg doramectin) / 33 kg body weight, which corresponds to a dose of 300 µg / kg body weight administered intramuscularly. A single treatment with the increased dose is sufficient to treat the clinical symptoms of Psoroptes scabies and to kill live mites. It is important that it is together animals kept must be treated at the same time and any sheep that may have come into contact with a sheep infected with Psoroptes ovis must be treated . For 14 days after treatment, infected treated and non-infected, untreated sheep must not be allowed to come into contact with each other. The body weight of the animals must be determined prior to treatment in order to ensure proper dosing.

Sterile tools must be used aseptically for treatment. In the case of group treatment of animals, a suitable automatic dosing device and a valved air intake device must be used. The syringe must be filled through a dry, sterile needle piercing the bottle
cap. The rubber stopper must not be pierced more than 20 times.
If the temperature of the preparation drops below 5°C, its viscosity increases, making it more difficult to administer, so it must be allowed to reach 15°C before injection.

**3.10 Symptoms of overdose (as well as - if applicable - emergency measures and antidotes)**
For cattle (given sc.) 25 times the recommended dose, for. (im.) 10 times and for sheep (im.) 15-it did not cause any side effects manifesting in clinical symptoms.

**3.11 Individual use restrictions and special conditions of use, including**
limiting the use of antimicrobial and antiparasitic veterinary medicinal products in order to reduce the risk of developing resistance

Not applicable.

**3.12 Food hygiene waiting period**
**Cattle:**

Meat and edible tissues: 70 days
The use of the product in cows producing milk intended for human consumption is not permitted.
It should not be used within 2 months before expected calving in pregnant cows and heifers that will produce milk for human consumption.

Sheep & Goats:.
Meat and edible tissues: 70 days
The product is not approved for use in sheep producing milk for human consumption.

It should not be used within 70 days of expected calving in pregnant ewes that will produce milk for human consumption.

## 4. PHARMACOLOGICAL PROPERTIES
**4.1 Veterinary ATC code: QP54AA03**
**4.2 Pharmacodynamics**

Doramectin is a new antiparasitic fermentation derivative belonging to the group of avermectins, which is structurally very similar to ivermectin. Both substances have a broad antiparasitic spectrum and cause similar paralysis of nematodes and arthropod ectoparasites. Although avermectins cannot be characterized by a single mechanism of action, it appears that the entire group works based on a common mechanism of action. In parasitic organisms, this effect is exerted through a special avermectin attachment point. The physiological response to avermectin binding is manifested in an increase in the chloride ion permeability of the cell

membrane. Chloride ion influx into motor neurons of nematodes or muscle cells of arthropods results in hyperpolarization, preventing signal transmission, resulting in paralysis.

Mammals, in which the receptor/channel complexes are located in the central nervous system, tolerate doramectin exceptionally well. Based on the low penetration of high molecular weight substances, such as avermectins, through the blood-brain barrier, it can be assumed that nervous system dysfunction can only be caused by high tissue concentrations.

**4.3 Pharmacokinetics**

Its maximum plasma concentration in cattle is reached 3 days after subcutaneous administration, and its elimination half-life is approx. 6 days.
Its maximum plasma concentration is reached 2 days after intramuscular administration in sheep and its elimination half-life is approx. 4.5 days.
Its maximum plasma concentration in is reached 3 days after intramuscular administration, and its elimination half- life is approx. 6 days.

**Environmental properties**

As with other macrocyclic lactones, doramectin has potential adverse effects on some non-target animal species. Excretion of doramectin at potentially toxic levels may take several weeks after treatment. The doramectin-containing faeces of treated animals emptied into the pasture may reduce the number of dung-forming organisms, which may have an adverse effect on the breakdown of the dung.

Doramectin is particularly toxic to aquatic organisms and can accumulate in sediments.

## 5. PHARMACEUTICAL PROPERTIES

**5.1 Major incompatibilities**

They are not known.

**5.2 Usability period**

The commercially packaged veterinary medicinal product can be used for: 3 years (stored at a temperature below 30°C).
Can be used after the first opening of the direct packaging: for 6 months (stored at a temperature below 30°C).

**5.3 Special storage requirements**

Keep away from light.
Store in the original packaging below 30°C.
It cannot be stored in the refrigerator. It must be protected from freezing.

**5.4 Nature and composition of direct packaging**

The preparation is available in 50 ml multi-dose amber vial with chlorobutyl rubber stoppers and aluminum caps and in plastic secondary packaging suitable.

**5.5 Unused veterinary medicinal products or veterinary medicinal products special precautions for the disposal of waste generated after application**

The unused veterinary medicinal product or the waste generated after the use of the veterinary medicinal product must be disposed of in accordance with the local regulations for the veterinary medicinal product and the national waste collection regulations.
The veterinary medicinal product must not enter natural waters, because doramectin can be dangerous for fish and other aquatic organisms.

**6. NAME OF THE MARKETING AUTHORIZATION HOLDER**

Nawan Laboratories (Pvt.) Ltd.

**7. MARKETING AUTHORIZATION NUMBER(S)**

Drug Reg. No.: 119878

**8. DATE OF FIRST ISSUANCE OF THE MARKETING AUTHORIZATION**

Date of Reg.: 23-01-2024

**9. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

A veterinary medicinal product that can only be issued with a veterinary prescription.

**MANUFACTURED BY:**

NAWAN LABORATORIES (PVT) LTD.

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