

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

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep

4.2. Indications for use specifying the target species

For cattle

For the control of infections caused by gastrointestinal worms, lungworms, eye worms, botflies, lice and mites.

The spectrum includes the following parasites:

Gastrointestinal worms (adult stages and fourth stage larvae): *Ostertagia ostertagi* (including inhibited stages)

O. lyrata (alleen volw. stadia); *I. lili* *Haemonchus*;

Trichostrongylus axis; *T. colubriformis*; *Cooperia oncophora*

C. pectinata (alleen volw. stadia); *C. punctata*; *C. surnabada* (syn. *mcmaster*)

Nematodirus helvetianus (couple treatment only) *N. spathiger* (adult stages only)

Bunostomum phlebotomum (adult stages only) *Strongyloides papillosus* (adult stages only) *Radiate oesophagostomy*

Trichuris spp. (volw. stadia only)

Lungworms (adult stages and fourth stage larvae):

Dictyocaulus viviparus

Eye worms (adult stages): *Thelazia* spp.

Gadflies (parasitic stages):

Hypoderma bovis *H. lineatum*

Blood-sucking lice:

Hematopinus Eurysternus

Linognathus calf

Capillatus Solenopotes

Scabies mites:

Psoroptes bovis

Sarcoptes scabiei

The veterinary medicinal product prevents (re)infection with the following parasites for the indicated period:

Species	Days
Bunostomum phlebotomum	22
Cooperia oncophora	21
Dictyocaulus viviparous	35
Haemonchus placei (adults only)	28
Linognathus vituli	28
Oesophagostomum radiatum	21
Ostertagia ostertagi	35
Psoroptes bovis	42
Trichostrongylus axei	28

For the sheep

For the control of infections of the following gastrointestinal roundworms, lungworms, scabies mites and nasal botflies:

Gastrointestinal roundworms (adults and fourth stage larvae (L4) unless otherwise stated) indicated):

Chabertina ovina

The Curtician's Cooperative (L4 only)

Cooperia oncophora

Haemonchus contortus

Nematodirus fillicollis (immature stages only)

Nematodirus battus (L4 only)

Nematodirus spathiger

Oesophagostomum venulosum

Ostertagia (Teladorsagia) girdled"

Strongyloides papillosis

Trichostrongylus axei

Trichostrongylus columbriformis

Trichostrongylus vitrinus

Trichostrongylus spp. (adult stages only)

* inhibited larval stages (L4) including strains resistant to benzimidazole sensitive.

Lungworms (adult stages)

Dictyocaulus filaria

Nasal botflies (first, second and third stage larvae) Oestrus sheep

Scabies mites

Psoroptes sheep

4.3. Contraindications

Do not use in dogs, as serious adverse reactions may occur. As with other avermectins, certain breeds of dogs, such as Collies, are particularly sensitive to doramectin and special precautions should be taken to avoid accidental consumption of the veterinary medicinal product. See section 4.5.

Do not use in case 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.

- under dosing, which may be due to underestimation of bodyweight, misadministration of the veterinary medicinal product, or lack of calibration of a 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 a different pharmacological class and having a different mode of action should be used.

Resistance to avermectins has been reported in *Teladorsagia* and *Haemonchus* in sheep within the EU. Therefore, the use of this veterinary medicinal 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

Special precautions for safe use in the target species:

When treating groups of animals, use a suitable automatic dosing device and vented draw-off apparatus.

Use sterile equipment and follow aseptic procedures. Avoid the introduction of contamination. Vial stoppers must not be breached more than one time. Swab the septum before removing each dose.

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

Do not smoke or eat while handling the veterinary medicinal product. Wash hands after use. In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

Advice to medical practitioners: In case of accidental self-injection specific symptoms have rarely been observed and therefore any case should be treated symptomatically.

Special precautions for the protection of the environment:

Doramectin is very toxic to dung fauna and aquatic organisms and may accumulate in sediments. The risk to aquatic ecosystems and dung fauna can be reduced by limiting too frequent and repeated use of doramectin (and products from the same anthelmintic class) in cattle and sheep.

The risk to aquatic ecosystems can be reduced by keeping treated livestock away from surface water for two to five weeks after treatment.

Other precautions:

Avermectins may occasionally cause signs of intolerance in non-target species. Cases of intolerance with fatal outcome have been described in dogs, mainly Collies, Old English Sheepdogs, as well as related breeds and crossbreeds, and in turtles and tortoises. Precautions should be taken to prevent these other animals from ingesting spilled veterinary medicinal product or accessing containers containing the veterinary medicinal product.

4.6. Adverse reactions (frequency and seriousness)

Cattle, sheep: none known.

Reporting adverse reactions is important. It allows for continuous monitoring of the safety of a veterinary medicinal product. The reports should be sent, preferably via a veterinarian, to either the marketing authorization holder or the national competent authority via the national reporting system. See the package leaflet for the relevant contact details.

4.7. Use during pregnancy and lactation or lay

Pregnancy and lactation:

Can be used in breeding cows and lactating cows.

Fertility: Can be used in breeding bulls.

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

No data available.

4.9. Dosage and administration route

Cattle: Subcutaneous use.

Sheep: Intramuscular use.

For the treatment and control of gastrointestinal roundworms, lungworms, eyeworms, warbles, lice and mange mites in cattle, and gastrointestinal roundworms and nasal bots in sheep, a single treatment of 1 ml (10 mg doramectin) per 50 kg bodyweight, equivalent to 200 micogram/kg bodyweight, administered in the region of the neck by subcutaneous injection in cattle and by intramuscular injection in sheep.

For the treatment of clinical signs of *Psoroptes ovis* (sheep scab) and elimination of living mites on sheep a single treatment of 1 ml per 33 kg bodyweight, equivalent to 300 microgram/kg body weight, administered in the neck by intramuscular injection. In addition, adequate bio-security measures should be implemented to prevent reinfestation. It is important to ensure that all sheep which have been in contact with infested sheep are treated.

To ensure administration of a correct dose, 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, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and overdosing.

Maximum injection volume for each target species:

Cattle: 5ml per injection site.

Sheep: 1.5ml per injection site.

The veterinary medicinal product may be used with automatic injection equipment with a vented draw-off system. Vial stoppers must not be broached more than one time.

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

In cattle, sheep overdoses up to 25, 10 and 10 times the maximum label recommended dose, respectively, resulted in no adverse clinical signs.

4.11. Special restrictions on use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products to limit the risk of development of resistance

Not applicable.

4.12. Withdrawal period:

Cattle:

Meat and offal: 70 days

Not approved for use in animals producing milk for human consumption.

Do not use in pregnant cows or heifers intended to produce milk for human consumption within 2 months before expected parturition.

Sheep:

Meat and offal: 70 days

Not approved for use in animals producing milk for human consumption.

Do not use in pregnant ewes intended to produce milk for human consumption within 70 days of expected parturition.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code. **QP54AA03**

5.1. Pharmacodynamics properties

Doramectin is an antiparasitic agent, isolated from fermentation of selected strains derived from the soil organism *Streptomyces avermitilis*. It is a macrocyclic lactone and is closely related to ivermectin. Both compounds share a wide spectrum of antiparasitic activity and produce a similar paralysis in nematodes and parasitic arthropods. Macrocyclic lactones activate glutamate gated chloride channels (GluCl) found on muscle membranes of the pharynx and particular neurones of invertebrate parasites. The selective toxicity of the macrocyclic lactones as antiparasitics is attributed to this action on channels that are not present in the host animal. There is evidence that the membranes of the muscle cells of the invertebrate female reproductive tract may be more sensitive to macrocyclic lactones than receptors on nerve or other muscle and this may explain the dramatic but temporary reduction in egg production in parasites not killed or eliminated by drug therapy.

5.2. Pharmacokinetic information

Maximum plasma concentration of doramectin occurs in 3 days with an elimination half-life of around 6 days in cattle, following subcutaneous administration.

Maximum plasma concentration of doramectin occurs in 2 days with an elimination half-life of 4.5 days in sheep, following either subcutaneous or intramuscular administration.

Environmental properties

Like other macrocyclic lactones, doramectin has the potential to adversely affect non-target organisms.

Following treatment, excretion of potentially toxic levels of doramectin may take place over a period of several weeks. Faeces containing doramectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

Doramectin is very toxic to aquatic organisms and may accumulate in sediments.

6. PHARMACEUTICAL INFORMATION

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 immediately, 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.

6.3. Nature and composition of primary conditioning

Cardboard box with glass injection vial (s).

Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.

Pack sizes: 50ml

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.: 119878

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 23-01-2024

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:



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