

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs (BE, IE)

Dorimec 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs (AT, DE, FR, HU, IT, NL, PL, PT, ES)

Dorimec Vet, Solution for Injection (DK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Doramectin 10.0 mg

Excipients

Butylhydroxyanisole (E320) 0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, yellowish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, Sheep and Pigs

4.2 Indications for use, specifying the target species

CATTLE:

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, lice, mange mites and ticks.

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

Ostertagia ostertagi (including inhibited larvae)

O.lyrata (adults only)

Haemonchus placei

Trichostrongylus axei

T.colubriformis

Cooperia oncophora

C.pectinata (adults only)

C.punctata

C.surnabada (syn. *mcmasteri*)

N.spathiger (adults only)

Bunostomum phlebotomum (adults only)

Strongyloides papillosus (adults only)

Oesophagostomum radiatum

Trichuris spp. (adults only)

Lungworms: (adults and fourth stage larvae)

Dictyocaulus viviparus

Eyeworms: (adults only)

Thelazia spp.

Warbles: (parasitic stages)

Hypoderma bovis

H. lineatum

Sucking lice:

Haematopinus eurysternus

Linognathus vituli

Solenopotes capillatus

Mange mites:

Psoroptes bovis

Sarcoptes scabiei

The product may also be used as an aid in the treatment of *Nematodirus helvetianus*, biting lice (*Damalinea bovis*), the tick *Ixodes ricinus* and the mange mite *Chorioptes bovis*.

Following product administration, efficacy against re-infection with the following parasites persists for the period indicated:

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

SHEEP:

For treatment of gastrointestinal roundworms, lungworms, nasal bots and mange mites

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

Bunostomum trigonocephalum (adults only)

Chabertia ovina

Cooperia curticei (L4 only)

C. oncophora

Gaigeria pachyscelis

Haemonchus contortus

Nematodirus battus (L4 only)

N. filicollis (adults only)

N. spathiger

*Ostertagia (Teladorsagia) circumcincta**

Ostertagia (Teladorsagia) trifurcata (adults only)

Oesophagostomum venulosum (adults only)

O. columbianum

Strongyloides papillosus

Trichostrongylus axei

T. colubriformis

T. vitrinus

Trichuris spp. (adults only)

*Inhibited larval stages (L4), including strains that are benzimidazole resistant, are also treated.

Lungworms (adults and fourth stage larvae (L4))

Cystocaulus ocreatus (adults only)

Dictyocaulus filaria

Muellerius capillaris (adults only)

Neostrongylus linearis (adults only)

Protostrongylus rufescens (adults only)

Nasal bots (1st, 2nd and 3rd instar larvae)

Oestrus ovis

Mange mites

Psoroptes ovis

PIGS:

For treatment of gastrointestinal roundworms, lungworms, kidney worms, sucking lice and mange mites in pigs.

Gastrointestinal roundworms (adults and fourth stage larvae)

Hyostrongylus rubidus

Ascaris suum

Strongyloides ransomi (adults only)

Oesophagostomum dentatum

Oesophagostomum quadrispinulatum

Lungworms

Metastrongylus spp. (adults only)

Kidney worms

Stephanurus dentatus (adults only)

Sucking Lice

Haematopinus suis

Mange Mites

Sarcoptes scabiei

The product protects pigs against infection or reinfection with *Sarcoptes scabiei* for 18 days.

4.3 Contraindications

Do not use in dogs, as severe adverse reactions may occur. In common with other avermectins, certain breeds of dog, such as collies, are especially sensitive to doramectin and particular care should be taken to avoid accidental consumption of the product. See section 4.5 i.

Do not use in cases of hypersensitivity to the active substance or 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 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* spp and *Haemonchus contortus* in sheep and in *Cooperia* spp. and *Ostertagia ostertagi* in cattle within the EU. A rise in the frequency of resistance of *Haemonchus* spp in cattle to ivermectin has been reported outside the EU. Resistance to macrocyclic lactones has been reported in *Psoroptes ovis*.

Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of roundworms and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals

Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoise. Care should be taken to avoid ingestion of spilled product or access to containers by these other species.

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

For treatment of individual pigs, the use of appropriate sized needles and disposable syringes should be advised by a veterinarian. For the treatment of piglets weighing 16 kg or less, a 1 ml disposable syringe graduated in increments of 0.1 ml or less should be used.

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. To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of the period of warble fly activity and before the larvae reach their resting site.

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

Do not smoke or eat while handling the product. Wash hands after use.

Take care to avoid accidental self-administration – seek medical attention should any specific signs be noticed. Advice to medical practitioners: In case of accidental self injection specific symptoms have rarely been observed and therefore any cases should be treated symptomatically.

Other precautions

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 avoiding too frequent and repeated use of doramectin (and products of the same anthelmintic class) in cattle and sheep.

The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

May be used in pregnant cows and ewes. The product is indicated for use in breeding and lactating sows and in breeding boars.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Subcutaneous use (cattle)

Intramuscular use (sheep and pigs)

For the treatment 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 mcg/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 mcg/kg bodyweight, 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.

For the treatment of *Sarcoptes scabiei* and gastrointestinal roundworms, lungworms, kidney worms and sucking lice in pigs, a single treatment of 1 ml per 33 kg bodyweight, equivalent to 300 mcg/kg bodyweight, administered by intramuscular injection.

Piglets weighing 16 kg or less should be dosed in accordance with the following table:

Body weight (kg)	Dose (ml)
Less than 4 kg	0.1 ml
5 - 7 kg	0.2 ml
8 - 10 kg	0.3 ml
11 - 13 kg	0.4 ml
14 - 16 kg	0.5 ml

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 over- dosing.

Maximum injection volume for each target species:

Cattle: 5 ml per injection site

Sheep: 1.5 ml per injection site

Pigs: 2.5 ml per injection site

The product may be used with automatic injection equipment with a vented draw-off system. When using an automatic device, vial stoppers must not be broached more than one time. For manual vial broachings, vial stoppers must not be broached more than 10 times for the 50 ml pack and not more than 25 times for the 250 ml and 500 ml packs.

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

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

4.11 Withdrawal period(s)

CATTLE:

Meat and offal: 70 days

Not permitted for use in lactating animals producing milk for human consumption.

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

SHEEP:

Meat and offal: 70 days

Not permitted for use in lactating animals producing milk for human consumption.

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

PIGS:

Meat and offal: 77 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides, macrocyclic lactones, avermectins.

ATC vet code: QP 54AA03.

5.1 Pharmacodynamic 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 roundworms and parasitic arthropods. Macrocyclic lactones activate glutamate gated chloride channels (GluCl) found on muscle membranes of the pharynx and particular neurones of invertebrate parasites. Entry of chloride ions into roundworm excitatory motor neurons or arthropod muscle cells results in hyperpolarization and elimination of the transmission signal which results in paralysis. 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 particulars

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 intramuscular administration.

Maximum plasma concentration of doramectin occurs in 3 days with an elimination half-life of around 6 days in pigs, following 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 PARTICULARS**6.1 List of excipients**

Ethyl Oleate

Sesame oil, refined

Butylhydroxyanisole (E320)

6.2 Major 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: 30 months.

Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Store in the original package in order to protect from light.

6.5 Nature and composition of immediate packaging

Type II amber glass multi-dose vials, with chlorobutyl rubber stoppers secured with an aluminium cap.

Package sizes:

Cardboard box containing 1 vial of 50 ml.

Cardboard box containing 1 vial of 250 ml.

Cardboard box containing 1 vial of 500 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Extremely dangerous for aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable