

Dectomax

Doramectin

10mg/ml Solution for Injection

1% w/v injectable solution

Product Description: Clear, colorless to pale yellow solution conforming to parenteral standards in amber glass vials.

Pharmacodynamics: 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.

Pharmacokinetics:

Maximum plasma concentration of doramectin occurs in pigs 3 days after intramuscular administration and in cattle 3 days after subcutaneous injection of Dectomax injectable solution. The elimination half-life is around six days.

Indications:

Cattle: Dectomax injectable solution is indicated for the treatment of parasitic infections and infestations due to the following species of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and psoroptic and sarcoptic mange mites:

Gastrointestinal Roundworms

Ostertagia ostertagi (adults, L4 and inhibited L4)

O. lyrata (adults only)

Haemonchus placei (adults and L4)

Trichostrongylus axei (adults and L4)

T. colubriformis (adults and L4)

Cooperia oncophora (adults and L4)
C. pectinata (adults only)
C. punctata (adults and L4)
C. surnabada (syn. *mcmasteri*) (adults and L4)
Nematodirus spathiger (adults only)
Bunostomum phlebotomum (adults only)
Strongyloides papillosus (adults only)
Oesophagostomum radiatum (adults and L4)
Trichuris ovis (adults only)

Lungworms
Dictyocaulus viviparus (adults and L4)

Eyeworms
Thelazia spp (adults only)

Grubs (migrating larvae)
Hypoderma bovis
H. lineatum

Sucking Lice
Haematopinus eurysternus
Linognathus vituli
Solenopotes capillatus

Mange Mites
Psoroptes bovis
Sarcoptes scabiei var. *bovis*

Dectomax injectable solution protects cattle against infection or reinfection with *Ostertagia ostertagi* and *Cooperia punctata* for at least 21 days and with *Dictyocaulus viviparus* for at least 28 days.

Swine: Dectomax injectable solution is indicated for the treatment of parasitic infections and infestations due to the following species of gastrointestinal roundworms, lungworms, kidney worms, sucking lice and sarcoptic mange mites:

Gastrointestinal Roundworms
Ascaris suum (adults and L4)
Oesophagostomum dentatum (adults and L4)
Oesophagostomum quadrispinulatum (adults and L4)
Strongyloides ransomi (adults only)
Hyostromylus rubidus (adults and L4)

Lungworms
Metastrongylus spp. (adults only)

Kidney Worms
Stephanurus dentatus (adults only)

Sarcoptic Mange Mites
Sarcoptes scabiei var. suis

Sucking Lice
Haematopinus suis

For effective mange eradication, care must be taken to prevent re-infestation from exposure to untreated animals or contaminated facilities.

Recommended Dose:

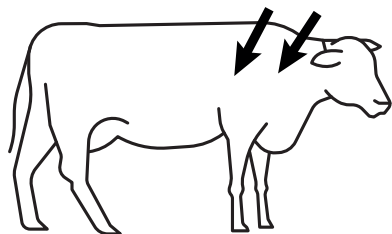
Cattle: Administer Dectomax injectable solution at a dosage of 200 mcg of doramectin per kg body weight. Each mL contains 10 mg of doramectin, sufficient to treat 50 kg of body weight.

Swine: Administer Dectomax injectable solution at a dosage of 300 mcg of doramectin per kg body weight. Each mL contains 10 mg of doramectin, sufficient to treat 34 kg of body weight.

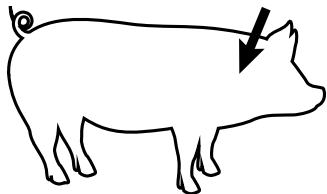
Dry, sterile equipment and aseptic procedures should be used when withdrawing and administering Dectomax injectable solution. The injection site should be cleaned and disinfected with alcohol before injection. The rubber stopper should also be disinfected with alcohol to prevent contamination of contents. For multiple treatments, either automatic injection equipment or an aspirating needle should be used. When the temperature of the formulation is below 5°C, the viscosity of the product increases and increased effort may be required for injecting. Syringeability may be improved by gently warming the injecting equipment and the product up to 15°C. Animals should be restrained to ensure that treatment can be properly administered.

Cattle: Administer Dectomax injectable solution by the subcutaneous or intramuscular route. Each injection should be made using a clean, dry 16 to 18-gauge needle. Subcutaneous injections should be administered into the neck region using needles 1/2 to 5/8" in length. Intramuscular injections should be administered into

a region of large muscle mass (preferably in the lateral neck region) using a 1½" needle. Not more than 10 mL should be injected at any one site.



Swine: Administer Dectomax injectable solution by the intramuscular route into the neck region using an 18 to 20-gauge needle 1/2 to 5/8" in length for young animals, and a 16 to 18-gauge needle 1 to 1½" in length for sows and boars.



Recommended Treatment Program: To effectively initiate control of mange and lice, it is important to treat all animals in the categories

below. After initial treatment, use Dectomax injectable solution regularly as follows:

Breeding Animals:

Sows: Treat 7 to 14 days prior to farrowing to minimize exposure of piglets to mites and lice.

Gilts: Treat 7 to 14 days prior to breeding. Treat 7 to 14 days prior to farrowing.

Boars: Treat a minimum of 2 times per year.

Feeder Pigs: Treat any new feeder pigs upon arrival at farm or before placement in clean quarters.

Weaners, Growers, Finishers: Weaner and grower / finisher pigs should be treated before placement in clean quarters.

Route of Administration:

Cattle: Subcutaneous or intramuscular. **Swine:** Intramuscular.

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.

Do not use in case of hypersensitivity to the active substance or any of the excipients.

Warning and Precautions:

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.

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.

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.

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

For Animal Use Only.

Controlled Medicine / Ubat Terkawal.

Keep out of reach of children / Jauhi dari kanak-kanak.

Interactions with Other Medicaments: None known.

Pregnancy and Lactation: Dectomax injectable solution is indicated for use in breeding and lactating sows and in breeding boars. May be used in pregnant cows.

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

Side Effects: None have been observed.

Symptoms and Treatment of Overdose: In cattle (SC route only) and pigs (IM only) overdoses up to 25 and 10 times respectively of the maximum label recommended dose resulted in no adverse clinical signs that could be attributed to treatment with doramectin.

Incompatibilities: None known.

Shelf Life: 3 years.

Storage Condition: Store below 30°C. Do not refrigerate or freeze. Protect from direct sunlight. Shelf life after first use: 90 days.

Withdrawal Period:

Treated animals must not be slaughtered for use as food for at least 40 days for cattle and 62 days for swine after the latest treatment with this drug.

This product must not be used in lactating dairy cows. Because a withdrawal time for milk has not been established, non-lactating dairy cows must not be treated within 2 months of calving.

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.

Packaging Available: 20 mL, 50 mL, 100 mL, 250 mL and 500 mL per bottle. Not all pack sizes are marketed.

Manufactured by:

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Product Registration Holder:

zoetis

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