1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax Veterinary

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 colourless, to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep

4.2 Indications for use, specifying the target species

Against Gastro-intestinal and Pulmonary nematodes and ectoparasites infesting bovines administered by subcutaneous injection. For treatment and control of the following gastrointestinal roundworms, lungworms, mange mites and nasal bots for sheep.

CATTLE:

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited larvae)
O.lyrata *
Haemonchus placei
Trichostrongylus axei
T.colubriformis
Cooperia oncophora
C.pectinata *
C.punctata
C.surnabada (syn. *mcmasteri)*
N.spathiger *
Bunostomum phlebotomum *
Strongyloides papillosus *
Oesophagostomum radiatum
Trichuris spp.*
*adults
Lungworms: (adults and fourth stage larvae)
Dictyocaulus viviparus
Eyeworms: (adults)
Thelazia spp.

Warbles: (parasitic stages)
Hypoderma bovis
H.lineatum
Sucking lice:
Haematopinus eurysternus
Linognathus vituli
Solenopotes capillatus
Mange mites:
Psoroptes bovis
Sarcoptes scabiei
Following product administration, efficacy against re-infection with the following parasites persists for the period indicated:

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

SHEEP:
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 controlled.
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

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.
Do not use in case 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 and Haemonchus in sheep within the EU. Therefore, the use of this 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 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.
Use sterile equipment and follow aseptic procedures. Avoid the introduction of contamination. Vial stoppers must not be broached 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 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.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:
https://sideeffects.health.gov.il/

4.7 Use during pregnancy, lactation or lay

May be used in pregnant cows and ewes.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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 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.

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

The 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 andsheep overdoses up to 25 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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES
Pharmacotherapeutic group: macrocyclic lactones, avermectins
ATCvet 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 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 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 either subcutaneous or intramuscular administration.

5.3 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
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
The expiry date of the product is indicated on the packaging materials
Shelf life after first opening the immediate container: 28 days.

6.4 Special precautions for storage
Do not store above 30 °C.
Keep out of the reach of children.

6.5 Nature and composition of immediate packaging
The product is supplied in 50 ml, 200 ml and 500 ml
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products
Extremely dangerous for fish and 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
Zoetis Israel Holding B.V., 5 Atir Yeda Street, Kfar Saba, Israel

8 MARKETING AUTHORISATION NUMBER(S)
083-73-92120-00

9 MANUFACTURER
Inovat Industria Farmaceutica LTDA
Av. Presidente Tancredo De Almeida Neves, 1555 Guarulhos, Sao Paulo, Brazil

10 DATE OF REVISION OF THE TEXT
This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in June 2020.