

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DECTOMAX 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Doramectin 10.0 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylhydroxyanisole (E320)	0.1mg
Ethyl Oleate	
Sesame oil	

Clear colourless, to pale yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle, sheep and pigs.

### 3.2 Indications for use for each target species

#### Cattle :

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

#### 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*)

*Nematodirus 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*

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

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

<b>Species</b>	<b>Days</b>
<i>Bunostomum phlebotomum</i>	22
<i>Cooperia oncophora</i>	21
<i>Dictyocaulus viviparus</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 and control of gastrointestinal roundworms, mange mites and nasal bots.

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)

*Nematodirus filicollis* (adults only)

*Nematodirus 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*

**Pigs:**

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

Gastrointestinal nematodes (adults and fourth stage larvae)

*Hyostrogylus 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 veterinary medicinal product protects pigs against infection or reinfection with *Sarcoptes scabiei* for 18 days.

**3.3 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 veterinary medicinal product. See section 3.5 “Other precautions”.

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

**3.4 Special warnings**

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.

### **3.5 Special precautions for use**

#### Special precautions for use in the target 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 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 cases 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 avoiding too frequent and repeated use of doramectin (and veterinary medicinal 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.

#### Other precautions:

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 veterinary medicinal product or access to containers by these other species.

### **3.6 Adverse events**

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details

### 3.7 Use during pregnancy, lactation or lay

#### Pregnancy and lactation:

Can be used in pregnant cows and ewes.

#### Fertility:

The veterinary medicinal product is indicated for use in breeding and lactating sows and in breeding boars.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

Cattle: Subcutaneous use.

Sheep: Intramuscular use.

Pigs: 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 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 nematodes, lungworms, kidney worms and sucking lice in pigs, a single treatment of 1 ml per 33 kg bodyweight, equivalent to 300 microgram/kg bodyweight, administered by intramuscular injection.

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

<b>Body weight (kg)</b>	<b>Dose (ml)</b>
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: 5ml per injection site.  
Sheep: 1.5ml per injection site.  
Pigs: 2.5ml 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.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

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.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable

### **3.12 Withdrawal periods**

#### **Cattle:**

Meat and offal: 70 days.

Not authorised for use in 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 authorised for use in 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.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code: QP 54AA03**

### **4.2 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.

### **4.3 Pharmacokinetics**

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.

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.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

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

### **5.3 Special precautions for storage**

Do not store above 30°C.

Protect from direct sunlight. Do not remove from the protective plastic overwrap.

### **5.4 Nature and composition of immediate packaging**

50 ml, 200 ml and 500 ml multi-dose Type II or Type III amber glass vials with chlorobutyl rubber stoppers and aluminium overcaps or in 250 ml multi-dose Type II amber glass vials with chlorobutyl rubber stoppers and aluminium overcaps.

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater or household waste.

Do not contaminate ponds, waterways or ditches with the product or used container.

The veterinary medicinal product should not enter water courses as doramectin is extremely dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

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

Zoetis Belgium S.A

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

VPA10387/019/001

**8. DATE OF FIRST AUTHORISATION**

09/12/2012

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

22/12/2023

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).