

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax Pour-On Solution for Cattle 5 mg/ml (UK)
Zearl Pour-On Solution for Cattle 5 mg/ml (IE)
Dectomax Pour-On Vet.(DK),
Dectomax Pour-on Solution for Cattle 5 mg/ml (BE)
Dectomax Pour on (DE, PT, LU, IT)
Zearl Pour-on (FR)
Dectomax Pour-On 5 mg/ml Solution for Cattle (AT)
Dectomax Pour-On Solution for Cattle 5 mg/ml(NL)
Dectomax Pour-on Solution 5 mg/ml for Cattle (ES)
Dectomax Pour-on Vet. 5 mg/ml Pour-On Solution(SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml Dectomax Pour-On Solution 5 mg/ml contains the following:

Active substance:

Doramectin 5 mg

Excipient(s):

Cetearyl octanoate	160.00 mg
Triethanolamine	0.5 mg
Isopropanol	to 1 ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on.
Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, sucking and biting lice, mange mites and hornfly in cattle.

Gastrointestinal roundworms (adults and fourth stage larvae)

Ostertagia ostertagi (*inc. inhibited larvae*)

*O. lyrata*¹

Haemonchus placei

Trichostrongylus axei
T. colubriformis
Cooperia oncophora
*C. punctata*¹
*C. surnabada*¹ (syn. *mcmasteri*)
*Bunostomum phlebotomum*¹
Oesophagostomum radiatum
Trichuris spp¹

¹ adults

Lungworms (adults and fourth stage larvae)

Dictyocaulus viviparus

Eyeworms (adults)

Thelazia spp

Warbles (parasitic stages)

Hypoderma bovis, *H. lineatum*

Biting lice

Damalinia (Bovicola) bovis

Sucking lice

Haematopinus eurystemus,

Linognathus vituli,

Solenopotes capillatus

Mange mites

Psoroptes bovis,

Sarcoptes scabiei,

Chorioptes bovis

Horn fly

Haematobia irritans

Duration of activity

Dectomax Pour-On protects cattle against infection or re-infection with the following parasites for the periods indicated.

<u>Species</u>	<u>Days</u>
<i>Ostertagia ostertagi</i>	35
<i>Cooperia oncophora</i>	28
<i>Dictyocaulus viviparus</i>	42
<i>Linognathis vituli</i>	49
<i>Oesophagostomum radiatum</i>	21
<i>Damalinia (Bovicola) bovis</i>	42
<i>Trichostrongylus axei</i>	28
<i>Solenopotes capillatus</i>	35

Dectomax Pour-On also controls horn flies (*Haematobia irritans*) for at least 42 days after treatment.

4.3 Contraindications

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dog, may occur.

Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving.

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

4.4 Special warnings for each target species

For external use only.

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.

Do not apply to areas of skin that are contaminated with mud or manure.

Therapeutic efficacy for internal and external parasites is not affected by heavy rainfall (2 cm in 1 hour) either before (20 minutes) or after (20 and 40 minutes) treatment. The influence of extreme weather conditions on efficacy is unknown.

4.5 Special precautions for use

i. 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.

To avoid secondary reactions due to death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer Dectomax Pour-on at the end of the period of warble fly activity and before the larvae reach their resting sites. Consult your veterinary surgeon on the correct timing of treatment.

- ii. 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.

Dectomax Pour-on may be irritating to human skin and eyes and users should be careful not to apply it to themselves or to other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

Highly Flammable - Keep away from heat, sparks, open flame or other sources of ignition.

4.6 Adverse reactions (frequency and seriousness)

In rare cases small skin lesions may occur at the administration site.

4.7 Use during pregnancy, lactation or lay

Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days prior to calving.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

A single treatment of 1 ml (5 mg doramectin) per 10 kg bodyweight, equivalent to 500 µg/kg bodyweight, applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.

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.

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

Overdoses up to 5 times the label recommended dose resulted in no clinical signs that could be attributed to treatment with doramectin.

4.11 Withdrawal period(s)

Meat and offal: 35 days.

Do not use in lactating cows used to produce milk for human consumption, or in dry cows or pregnant dairy heifers within 60 days prior to calving

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic Products Insecticides and Repellents/Endectocides

ATCvet Code: QP 54AA03

5.1 Pharmacodynamic properties

Doramectin is a fermentation-derived antiparasitic agent, which belongs to the avermectin class, and is closely related structurally to ivermectin. Both compounds share a wide spectrum of antiparasitic activity and produce a similar paralysis in nematodes and parasitic arthropods. Whilst it is not possible to assign a single mode of action to the avermectins, it is likely that the entire series share a common mechanism. In parasitic organisms the effect is mediated through a specific avermectin-binding site. The physiological response to avermectin binding is an increase in membrane permeability to chloride ions. In invertebrate nervous tissue an influx of chloride ions into the excitatory motor neurone in nematodes or muscle cell of arthropods results in hyperpolarisation and the elimination of signal transmission with resulting paralysis.

5.2 Pharmacokinetic particulars

Maximum plasma concentration of doramectin occurs in cattle approximately 9 days after topical administration of Dectomax Pour-On. An (apparent) elimination half-life of around 10 days results in sustained doramectin concentrations, which protect animals from parasitic infection and re-infection for extended periods following treatment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetearyl octanoate
Triethanolamine
Isopropanol

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

6.4. Special precautions for storage

Store at temperatures below 30 °C. Do not refrigerate.
Protect from light.

6.5 Nature and composition of immediate packaging

Dectomax Pour-On will be supplied in:

- 250 ml and 1 L multi-dose high-density polyethylene bottles with screw-top lids and dosing cups

and

- 2.5 L, 3 L and 5 L multi-dose high-density polyethylene bottles with screw-top lids and draw-off adaptor.

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 fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco Animal Health
Eli Lilly & Company Limited
Lilly House
Priestly Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER(S)

Vm 00006/4122

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th February 1997 (First Authorisation)
17th December 2007 (Renewal)

10. DATE OF REVISION OF THE TEXT

Date: December 2011

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.