SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dectomax 5 mg/ml Pour-on Solution for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance
Doramectin 5.0 mg

Excipient
Butylated hydroxytoluene not more than 0.05 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-on solution.

Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For treatment of infestations 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 phlebotomum1
Oesophagostomum radiatum

Trichuris spp.[1]

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

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

The product 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 dogs, may occur.

Do not use in cases of hypersensitivity to the active substance or any of the excipients.
See section 4.5.

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).

Resistance to doramectin and other avermectins has been reported in gastro-intestinal nematodes, especially *Cooperia oncophera* and *Ostertagia ostertagi*, in cattle. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of the target nematodes and recommendations on how to limit further selection for resistance to anthelmintics**.**
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

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 the product 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.

Disease associated with warble fly is notifiable in some regions.

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

People with known hypersensitivity to the doramectin should avoid contact with the product. Do not smoke or eat while handling the product. Wash hands after use. The product may be irritating to human skin and eyes and users should be careful not to apply it to themselves or to other people. Operators should wear impermeable rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after every use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If irritation persists, seek medical attention. If accidental eye exposure occurs, flush the eyes immediately with clean water and seek medical attention immediately. Avoid accidental inhalation of this product, as this may cause drowsiness and dizziness. Use only in well ventilated areas or outdoors.
Highly Flammable - Keep away from heat, sparks, open flame or other sources of ignition.

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 products of the same anthelmintic class) in cattle.

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

Other precautions
Not applicable

4.6 Adverse reactions (frequency and seriousness)

Target species: Cattle

Very rare 1 to 10 animals / 10,000 animals treated):	Application site reaction NOS

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 also section 16 of the package leaflet for contact details.

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 Amount(s) 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 tail head.
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.

Dosage table

Body-weight (kg)	Dose Volume (ml)	Doses per 1 Litre Pack	Doses per 2.5 Litre Pack	Doses per 3 Litre Pack	Doses per 5 Litre Pack
150	15	66	166	200	333
200	20	50	125	150	250
250	25	40	100	120	200
300	30	33	83	100	166
350	35	28	71	85	142
400	40	25	62	75	125
450	45	22	55	66	111
500	50	20	50	60	100
600	60	16	41	50	83
700	70	14	35	42	71

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.
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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Pharmacotherapeutic group: macrocyclic lactones, avermectins

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 the product. 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.

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

Butylated hydroxytoluene
Triethanolamine
Cetostearyl Octanoate
Isopropyl alcohol

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: 5 years
Shelf life after first opening the immediate packaging: 1 year

6.4 Special precautions for storage

Do not refrigerate
Protect from light

6.5 Nature and composition of immediate packaging

The product will be supplied in:
- 1 L, 2.5 L, 3 L, 5 L, 6 L (5L + 1 L) and 8 L (5 L + 3 L) high-density polyethylene bottles with a tamper evident cap in a carton box.
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

Medicines should not be disposed of via wastewater.
The veterinary medicinal product should not enter water courses as doramectin may be dangerous for fish and other aquatic organisms. 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

C&H Generics Limited
c/o Michael McEvoy & Co.
Seville House
New Dock Street
Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 40162/3001

9. DATE OF FIRST AUTHORISATION

24 August 2023

10. DATE OF REVISION OF THE TEXT

August 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription

Approved 24 August 2023