Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 5 mg/ml Pour-on Solution for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance
Doramectin 5.0 mg

Excipients
For a 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 phlebotomum[1]
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

Mangemites
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.i.

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

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 Hypodermalarvae 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.

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

Persons with known hypersensitivity to the active substance 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 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. Use only in well ventilated areas or outdoors.

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

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 reduced by keeping treated cattle away from water bodies for two to five weeks after treatment.

4.6 Adverse reactions (frequency and seriousness)

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 interactions

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 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.

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 or IMMUNOLOGICAL PROPERTIES

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

Cetostearyl Octanoate
Trolamine
Isopropyl alcohol
Butylhydroxytoluene

6.2 Major incompatibilities

None known.

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

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

The product will be supplied in:
1 L, 2.5 L, 3 L, 5 L, 6L (5L+1L) and 8L (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 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

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/166/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 April 2021

10 DATE OF REVISION OF THE TEXT