Chanelle Pharma
Telephone: +353 91 84 17 88
Website: www.chanellepharma.com
Email: reception@chanellegroup.ie

Doramax 5 mg/ml Pour-on Solution for Cattle

Species: Cattle

Therapeutic indication: **Pharmaceuticals:** Miscellaneous

Active ingredient: Doramectin

Product: Doramax 5 mg/ml Pour-on Solution for Cattle

Product index: Doramax

Cattle - meat: 35 days.

Withdrawal notes: 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.

Notes:
Pharmacotherapeutic group: macrocyclic lactones, avermectins

Incorporating:

Presentation

Pour-on solution.

Clear, colourless solution.

Uses

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

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.

Dosage and administration

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	Doses per 6 Litre Pack	Doses per 8 Litre Pack
150	15	66	166	200	333	400	533
200	20	50	125	150	250	300	400
250	25	40	100	120	200	240	320
300	30	33	83	100	166	200	266
350	35	28	71	85	142	171	228
400	40	25	62	75	125	150	200
450	45	22	55	66	111	133	177
500	50	20	50	60	100	120	160
600	60	16	41	50	83	100	133
700	70	14	35	42	71	85	114

Contra-indications, warnings, etc

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.

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).

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.

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 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 irritation persists, seek medical attention. If accidental eye exposure occurs, flush the eyes immediately with clean water and get medical attention. 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.

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 five weeks after treatment.

Use during pregnancy, lactation or lay

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

Pharmaceutical precautions

Do not refrigerate

Protect from light

Legal category

Legal category: POM-VPS

Packaging quantities

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

Marketing Authorisation Holder (if different from distributor)

C&H Generics Limited

c/o Michael McEvoy & Co.

Seville House

New Dock Street

Galway

Ireland

Further information

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

Marketing Authorisation Number

Vm 40162/4038

Significant changes

GTIN

GTIN: ------