1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 5 mg/ml Pour-on Solution for Cattle (IE)
Dorimec 5 mg/ml Pour-on Solution for Cattle (CZ, FR, HU, NL, PL, RO, SI)
Dectomax 5 mg/ml Pour-on Solution for Cattle (BE, DE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Doramectin 5.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Cetostearyl octanoate
Trolamine
Isopropyl alcohol

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (inc. inhibited larvae)
O. lyrata (adults only)
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata (adults only)
C. surnabada (syn. mcmasteri) (adults only)
Bunostomum phlebotomum (adults only)
Oesophagostomum radiatum
Trichuris spp. (adults only)

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 flies: *Haematobia irritans*

Duration of activity
Following veterinary medicinal 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 veterinary medicinal product also controls horn flies (*Haematobia irritans*) for at least 42 days after treatment.

3.3 Contraindications

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

The veterinary medicinal 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.

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).

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 veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For external use only.

To avoid secondary reactions due to death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer the veterinary medicinal 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:

People with known hypersensitivity to doramectin should avoid contact with the veterinary medicinal product.
Do not smoke or eat while handling the veterinary medicinal product.
Wash hands after use.
The veterinary medicinal product may be irritating to human skin and eyes and users should be careful not to apply it to themselves or to other persons.
Personal protective equipment consisting of rubber gloves and boots with a waterproof coat should be worn when handling the veterinary medicinal 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.

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.

The risk to aquatic ecosystems will be 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

Cattle:

Rare (1 to 10 animals / 10 000 animals treated):	Application site lesion[1]

[1]Small.

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:

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Pour-on use.

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 a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

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.

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

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

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

Meat and offal: 35 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP54AA03

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Maximum plasma concentration of doramectin occurs in cattle approximately 9 days after topical administration of the veterinary medicinal 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.

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

None known.

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medicinal product will be supplied in high-density polyethylene bottles with a tamper evident cap in a carton box.

Pack sizes: 1 L, 2.5 L, 3 L, 5 L, 6 L (5 L+ 1 L) and 8 L (5 L + 3 L)

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.

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

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box for 1 L, 2.5 L, 3 L, 5 L, 6 L & 8 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 5 mg/ml Pour-on solution (IE)
Dorimec 5 mg/ml Pour-on Solution (CZ, FR, HU, NL, PL, RO, SI)
Dectomax 5 mg/ml Pour-on Solution (BE, DE)

2. STATEMENT OF ACTIVE SUBSTANCES

Doramectin 5 mg/ml

3. PACKAGE SIZE

1 L
2.5 L
3 L
5 L
6 L
8 L

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

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.

Body weight (kg)	Dose Volume (ml)	Doses per 1 L Pack	Doses per 2.5 L Pack	Doses per 3 L Pack	Doses per 5 L Pack	Doses per 6 L Pack	Doses per 8 L 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

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 35 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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 1 year.

Once opened, use by……

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE bottle for 1 L, 2.5 L, 3 L, 5 L, 6 L & 8 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 5 mg/ml Pour-on solution (IE)
Dorimec 5 mg/ml Pour-on Solution (CZ, FR, HU, NL, PL, RO, SI)
Dectomax 5 mg/ml Pour-on Solution (BE, DE)

2. STATEMENT OF ACTIVE SUBSTANCES

Doramectin 5 mg/ml

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Pour-on use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 35 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.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 1 year.

Once opened, use by……

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Doramax 5 mg/ml Pour-on Solution for Cattle (IE)
Dorimec 5 mg/ml Pour-on Solution for Cattle (CZ, FR, HU, NL, PL, RO, SI)
Dectomax 5 mg/ml Pour-on Solution for Cattle (BE, DE)

2. Composition

Each ml contains:

Active substance :
Doramectin 5.0 mg

Clear, colourless solution.

3. Target species

Cattle.

4. Indications for use

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

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (inc. inhibited larvae)
O. lyrata (adults only)
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata (adults only)
C. surnabada (syn. mcmasteri) (adults only)
Bunostomum phlebotomum (adults only)
Oesophagostomum radiatum
Trichuris spp. (adults only)

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 flies: *Haematobia irritans*

Duration of activity:
Following the veterinary medicinal 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 veterinary medicinal product also controls horn flies (*Haematobia irritans*) for at least 42 days after treatment.

5. Contraindications

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

The veterinary medicinal 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.

6. Special warnings

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).

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 veterinary medicinal 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 safe use in the target species:
For external use only.

To avoid secondary reactions due to death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer the veterinary medicinal 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 doramectin should avoid contact with the veterinary medicinal product.
Do not smoke or eat while handling the veterinary medicinal product.
Wash hands after use.
The veterinary medicinal product may be irritating to human skin and eyes and users should be careful not to apply it to themselves or to other persons.
Personal protective equipment consisting of rubber gloves and boots with a waterproof coat should be worn when handling the veterinary medicinal 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.

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.

The risk to aquatic ecosystems will be 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.

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

Interaction with other medicinal products and other forms of interaction:
None known.

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

Major incompatibilities:
None known.

7. Adverse events

Cattle:

Rare (1 to 10 animals / 10 000 animals treated):	Application site lesion[1]

[1]Small.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

Pour-on use.

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.

Body weight (kg)	Dose Volume (ml)	Doses per 1 L Pack	Doses per 2.5 L Pack	Doses per 3 L Pack	Doses per 5 L Pack	Doses per 6 L Pack	Doses per 8 L 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

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

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.

10. Withdrawal periods

Meat and offal: 35 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.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 1 year.

12. Special precautions for disposal

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

This 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes: 1 L, 2.5 L, 3 L, 5 L, 6L (5 L+ 1 L) and 8 L (5 L + 3 L)
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea, Co. Galway,
Ireland
Telephone: +353 (0)91 841788
E-mail: vetpharmacoviggroup@chanellegroup.ie

<Local representatives <and contact details to report suspected adverse events>:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>