ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE} carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 5 mg/ml Pour-on solution for cattle.

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains: Doramectin 5 mg

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle

6. INDICATION(S)

TREATS INFESTATIONS OF
✓ GASTROINTESTINAL ROUNDWORMS ✓ LUNGWORMS
✓ EYEWORMS ✓ WARBLES ✓ SUCKING AND BITING LICE ✓ MANGE MITES ✓ HORNFLY

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical use.
Read the package leaflet before 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.

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

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Once opened use within 1 year.

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate
Protect from light

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription

POM-VPS¤ ¤

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Distributed in the United Kingdom by:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway, Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 40162/4038

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{NATURE/TYPE} label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 5 mg/ml Pour-on solution for cattle.

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains: Doramectin 5 mg

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle

6. INDICATION(S)

TREATS INFESTATIONS OF
✓ GASTROINTESTINAL ROUNDWORMS ✓ LUNGWORMS
✓ EYEWORMS ✓ WARBLES ✓ SUCKING AND BITING LICE ✓ MANGE MITES ✓ HORNFLY

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical use.
Read the package leaflet before 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.

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

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Once opened use within 1 year.

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate
Protect from light

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription

POM-VPS¤ ¤

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Distributed in the United Kingdom by:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway, Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 40162/4038

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 5 mg/ml Pour-on Solution for Cattle
Doramectin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance
Doramectin 5.0 mg

Pour-on solution

Clear, colourless solution.

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

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).>

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF 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.

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
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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 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.

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.

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not refrigerate
Protect from light
Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 1 year

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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.

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.

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.

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.

Pregnancy and lactation:
See section 10.

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

Overdose (symptoms, emergency procedures, antidotes):
Overdoses up to 5 times the label recommended dose resulted in no clinical signs that could be attributed to treatment with Doramectin.

Incompatibilities:
None known

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

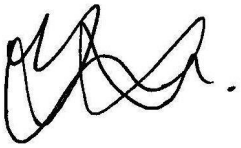
November 2020

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.

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



Approved: 24 November 2020