PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND IMMEDIATE PACKAGE

Carton (50 ml, 250 ml, 500 ml)
Label (250 ml, 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DORAMAX 10 mg/ml Solution for Injection for Cattle and Sheep
Doramectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Doramectin 10 mg/ml

3. PACKAGE SIZE

50 ml
250 ml
500 ml.

4. TARGET SPECIES

Cattle and Sheep.

5. INDICATIONS

Cattle:
Dosage 1 ml/50 kg by subcutaneous injection. For the treatment and control of gastrointestinal roundworms, lungworms, eye-worms, warbles, lice and mange mites in cattle.

Sheep:
For the treatment and control of *Psoroptes ovis* (sheep scab mite) and *Nematodirus battus,* a dosage of 1 ml/33kg bodyweight should be used by intramuscular injection.
For the treatment of gastrointestinal roundworms and nasal bots in sheep a dosage of 1 ml/50 kg by intramuscular injection.

6. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

7. WITHDRAWAL PERIOD(S)

Cattle and Sheep:
Meat and offal: 70 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.
Do not use in pregnant ewes, which are intended to produce milk for human consumption, within 70 days of expected parturition.

8. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.
Once broached use by…..

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.
Do not freeze. Do not refrigerate.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

C&H Generics Limited

<u>Distributed in the United Kingdom by:</u>
CHANELLE VET UK LTD,
483 Green Lanes,
London,
N13 4BS

14. MARKETING AUTHORISATION NUMBER(S)

Vm 40162/3003

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

EXTREMELY DANGEROUS to fish and aquatic life.
Do not contaminate ponds, waterways or ditches with the product or used container.
Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS

Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DORAMAX
Doramectin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Doramectin 10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.
Once broached use by…..

5. ROUTE(S) OF ADMINISTRATION

SC or IM.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET FOR:

Doramax 10 mg/ml Solution for Injection for Cattle and Sheep

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 10 mg/ml Solution for Injection for Cattle and Sheep

2. COMPOSITION

Each ml contains:

Active Substance
Doramectin 10.0 mg

Excipients
Butylhydroxyanisole (E320) 0.1 mg
Clear, yellowish solution for injection.

3. TARGET SPECIES

Cattle and sheep

4. INDICATIONS FOR USE

CATTLE
For treatment of infestations of gastrointestinal roundworms, lungworms, eyeworms, warbles, lice and mange mites.

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

Lungworms (adults and fourth stage larvae)
Dictyocaulus viviparus

Eyeworms (adults)
Thelazia spp

Warbles (parasitic stages)
Hypoderma bovis,
H. lineatum

Sucking lice
Haematopinus eurystemus,
Linognathus vituli,
Solenopotes capillatus

Mange mites
Psoroptes bovis,
Sarcoptes scabiei,

May also be used as an aid in the control of *Nematodirus helvetianus,* biting lice (*Damalinia bovis*) and the mange mite *Chorioptes bovis.*

The pharmacokinetics of Dectomax solution for injection allow protection of cattle against infection or re-infection with *Ostertagia ostertagi* for up to 35 days, *Cooperia oncophora* up to 21 days, *Dictyocaulus viviparus* up to 35 days, *Bunostomum*
phlebotomum up to 22 days, *Oesophagostomum radiatum* up to 21 days, *Trichostrongylus axei* up to 28 days, *Linognathus vituli* 28 days and *Psoroptes bovis* 42 days.
To obtain optimal benefits from the action of DORAMAX Solution for Injection, it is recommended that cattle which are set-stocked should be treated at turnout and eight weeks later. Studies have demonstrated that, used in this way, DORAMAX will reduce the build-up of infective larvae on pasture and can protect animals from parasitic gastro-enteritis and parasitic bronchitis throughout the grazing season. To obtain these results, all animals must be included in the programme and untreated cattle must not be introduced on the pasture. Treated cattle should always be monitored according to good husbandry practices. Treatment with DORAMAX Solution for Injection at turnout and eight weeks later of cattle set-stocked for the grazing season can protect against clinical disease caused by lungworm and may allow the development of naturally acquired immunity. However, due to the unpredictable nature of lungworm epidemiology, clinical signs of lungworm disease may on occasion be seen, particularly towards the end of the grazing season, if the
season is long. If this occurs, cattle should be further treated with an anthelmintic effective against lungworm.

SHEEP:

For the treatment and control of *Psoroptes ovis* (sheep scab mite) and *Nematodirus battus* at the recommended dose rate of 300 mcg/kg bodyweight (1 ml/33 kg).
The product is indicated for the following species of gastrointestinal roundworms and nasal bots in sheep at the recommended dose rate of 200 mcg per kilogram bodyweight (1 ml/50 kg):

Gastrointestinal roundworms (Adults and fourth stage larvae (L4) unless otherwise indicated):
Chabertia ovina (adults only)
Cooperia curticei (L4 only)
C. oncophora
Gaigeria pachycelis
Haemonchus contortus
Nematodirus battus (L4 only)[1]
Ostertagia (Teladorsagia) circumcincta *
Oesophagostomum columbianum
Strongyloides papillosus
Trichostrongylus axei
Trichostrongylus colubriformis
Trichostrongylus vitrinus
Trichuris spp (Adults only)

* Inhibited larval stages (L4) including strains that are benzimidazole resistant, are also controlled.

[1] For effective treatment and control of both adults and L4 larvae of *Nematodirus battus* a dose rate of 300 mcg/kg is required.

Lungworms
Dictyocaulus filaria (Adults only)

Nasal bots (1st, 2nd and 3rd instar larvae)
Oestrus ovis

5. CONTRAINDICATIONS

Can be used in pregnant non-dairy ewes.
Assess bodyweight as accurately as possible before calculating dosage.
Administer the calculated dose accurately, particularly when treating young lambs.
Doramax solution for injection should not be used in dogs, as severe reactions may occur. In common with other avermectins, certain breeds of dogs, such as collies, are especially sensitive to doramectin and particular care should be taken to avoid accidental consumption of the product.
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.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelrnintics 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 another pharmacological class and having a different mode of action should be used. Resistance to doramectin (an avermectin) has been reported in *Teladorsagia* and *Haemonchus* in sheep within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

6. SPECIAL WARNING(S)

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

Operator warnings
Do not eat, drink or smoke while handling the product. Wash hands after use.
Take care to avoid accidental self-injection - seek medical attention should any specific signs be noticed.
Advice to Doctors: in cases of accidental self-injection, specific symptoms have rarely been observed and therefore any cases should be treated symptomatically.

Special precautions for the protection of the environment:
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 nontarget 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 and sheep.
The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for five weeks after treatment.

7. ADVERSE EVENTS

None known

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><the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system <{national system details}

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

Cattle
Administer Doramax solution for injection at a dosage of 200 mcg doramectin per kilogram of bodyweight by the subcutaneous route. Each ml contains 10 mg of doramectin, sufficient to treat 50 kg of bodyweight. Each injection should be made into the neck region using a dry sterile 16 to 18 gauge needle, 15 mm in length.
Sheep
For the treatment and control of *Psoroptes ovis* (sheep scab mite) and *Nematodirus battus,* a dosage of 300 mcg/kg bodyweight should be used by the intramuscular route. Each ml contains 10 mg of doramectin, sufficient to treat 33 kg of bodyweight. In adult sheep each intramuscular injection should be made using a dry sterile 16 to 18 gauge needle, 25 mm in length.
(For the treatment of individual sheep a 2 ml disposable syringe calibrated in increments of 0.1 ml should be used). Suggested dose rates for *Psoroptes ovis* (sheep scab mite) and *Nematodirus battus* 1 ml/33 kg bodyweight (300 mcg/kg).

Sheep over 16 kg bodyweight:

Bodyweight	Dose
17 - 25kg	0.75ml
26 - 33 kg	1.0 ml
34 - 41 kg	1.25ml
42 - 50 kg	1.5 ml
51 - 58 kg	1.75ml
59 - 66kg	2.0 ml
67 - 74 kg	2.25 ml
75 - 83 kg	2.5 ml
84 - 91 kg	2.75 ml
92 - 99kg	3.0 ml

In young lambs of less than 16 kg bodyweight seek veterinary advice regarding the use of appropriate sized needles and of 1 ml disposable syringes graduated in increments of 0.1 ml or less. Suggested dose rates at 1 ml/33 kg bodyweight (300 mcg/kg) in young lambs:

Bodyweight	Dose

Less than 4 kg	0.1 ml
5 - 6 kg	0.2 ml
7 - 10 kg	0.3 ml
11 - 13 kg	0.4 ml
14 - 16 kg	0.5 ml

For treatment of gastro-intestinal roundworms and nasal bots, administer Doramax solution for injection once at a dosage of 200 mcg doramectin per kilogram of bodyweight by the intramuscular route. Each ml contains 10 mg of doramectin, sufficient to treat 50 kg of bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

Doramax is a clear, sterile solution. In common with other non-aqueous formulations the product contains no antimicrobial preservative. Dry, sterile equipment and aseptic procedures should therefore be used when administering Doramax to animals.
Swab the septum before removing the dose. When the temperature of the formulation is below 5°C, syringeability may be improved by gently warming the injecting equipment and product.
When treating groups of animals, use only the Doramax automatic dosing device and vented draw-off apparatus. When treating individual animals syringes must be filled from the vial through a dry, sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than 20 times.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment.

Cattle - Meat and offal: 70 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.

Sheep - Meat and offal: 70 days
Not permitted for use in lactating animals producing milk for human consumption.
Do not use in pregnant ewes, which are intended to produce milk for human consumption, within 70 days of expected parturition

11. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.
Do not freeze. Do not refrigerate.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

EXTREMELY DANGEROUS to 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 products should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Legal category:

POM-VPS

Veterinary medicinal product subject to prescription

Anthelmintic Class:

3-AV

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 40162/3003

Package quantities: Multi-dose vials of 50 ml, 250 ml and 500 ml.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

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

Ireland

Manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

Distributed in the United Kingdom by
CHANELLE VET UK LTD
483 Green Lanes
London
N13 4BS

17. OTHER INFORMATION

Sheep scab (caused by *Psoroptes avis)* is an extremely contagious disease. In view of sheep scab control requirements in the UK, treatment with 300 mcg doramectin per kg bodyweight is recommended to ensure elimination of all mites. In addition, where possible, adequate bio-security measures should be implemented to prevent re-infestation. Ensure that all sheep which have been in contact with infested sheep are treated. After treatment, contact between treated infected and untreated uninfected flocks must be avoided for at least 14 days. When used for scab treatment in sheep, Doramax solution for injection is also effective against certain gastro-intestinal roundworms, and this treatment may form part of a worm control programme in the flock.

Gavin Hall

Approved: 04 October 2024