ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs (BE, IE, HR, RO)
Dorimec 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs (AT, DE, FR, HU, IT, NL, PL, PT, ES)
Dorimec Vet, Solution for Injection (DK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each ml contains:
Doramectin 10.0 mg

Excipients:
Each ml contains:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E320)	0.1 mg
Ethyl Oleate	-
Sesame oil, refined	-

Clear, yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, Sheep and Pigs.

3.2 Indications for use for each target species

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

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

Lungworms: (adults and fourth stage larvae)
Dictyocaulus viviparus

Eyeworms: (adults only)
Thelazia spp.

Warbles: (parasitic stages)
Hypoderma bovis
H.lineatum

Sucking lice:
Haematopinus eurysternus
Linognathus vituli
Solenopotes capillatus

Mange mites:
Psoroptes bovis
Sarcoptes scabiei

The product may also be used as an aid in the treatment of *Nematodirus helvetianus*, biting lice (*Damalinia bovis*), the tick *Ixodes ricinus* and the mange mite *Chorioptes bovis*.
Following product administration, efficacy against re-infection with the following parasites persists for the period indicated:

Species	**Days**
Bunostomum phlebotomum	22
Cooperia oncophora	21
Dictyocaulus viviparous	35
Haemonchus placei (adults only)	28
Linognathus vituli	28
Oesophagostomum radiatum	21
Ostertagia ostertagi	35
Psoroptes bovis	42
Trichostrongylus axei	28

SHEEP:
For treatment of gastrointestinal roundworms, lungworms, nasal bots and mange mites

Gastrointestinal roundworms (adults and fourth stage larvae (L4) unless otherwise indicated):
Bunostomum trigonocephalum (adults only)
Chabertia ovina
Cooperia curticei (L4 only)
C.oncophora
Gaigeria pachyscelis
Haemonchus contortus
Nematodirus battus (L4 only)
N.filicollis (adults only)
N.spathiger
*Ostertagia (Teladorsagia) circumcincta**
Ostertagia (Teladorsagia) trifurcata (adults only)
Oesophagostomum venulosum (adults only)
O.columbianum
Strongyloides papillosus
Trichostrongylus axei
T.colubriformis
T.vitrinus
Trichuris spp. (adults only)

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

Lungworms (adults and fourth stage larvae (L4))
Cystocaulus ocreatus (adults only)
Dictyocaulus filaria
Muellerius capillaris (adults only)
Neostrongylus linearis (adults only)
Protostrongylus rufescens (adults only)

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

Mange mites
Psoroptes ovis

PIGS:
For treatment of gastrointestinal roundworms, lungworms, kidney worms, sucking lice and mange mites in pigs.

Gastrointestinal roundworms (adults and fourth stage larvae)
Hyostrongylus rubidus
Ascaris suum
Strongyloides ransomi (adults only)
Oesophagostomum dentatum
Oesophagostomum quadrispinulatum

Lungworms
Metastrongylus spp. (adults only)

Kidney worms
Stephanurus dentatus (adults only)

Sucking Lice
Haematopinus suis

Mange Mites
Sarcoptes scabiei

The product protects pigs against infection or reinfection with *Sarcoptes scabiei* for 18 days.

3.3 Contraindications

Do not use in dogs, as severe adverse reactions may occur. In common with other avermectins, certain breeds of dog, such as collies, are especially sensitive to doramectin and particular care should be taken to avoid accidental consumption of the product. See section 3.4.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

3.4 Special warnings

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.

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.

Resistance to avermectins has been reported in *Teladorsagia spp* and *Haemonchus contortus* in sheep and in *Cooperia spp*. and *Ostertagia ostertagi* in cattle within the EU. A rise in the frequency of resistance of *Haemonchus spp* in cattle to ivermectin has been reported outside the EU. Resistance to macrocyclic lactones has been reported in *Psoroptes ovis*. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of roundworms and recommendations on how to limit further selection for resistance to anthelmintics.

3.5 Special precautions for use

Special precautions for safe use in the target species:

When treating groups of animals, use a suitable automatic dosing device and vented draw-off apparatus.
For treatment of individual pigs, the use of appropriate sized needles and disposable syringes should be advised by a veterinarian. For the treatment of piglets weighing 16 kg or less, a 1 ml disposable syringe graduated in increments of 0.1 ml or less should be used.
Use sterile equipment and follow aseptic procedures. Avoid the introduction of contamination. Vial stoppers must not be broached more than one time. Swab the septum before removing each dose.
To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in 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 site.

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

Do not smoke or eat while handling the product. Wash hands after use.
Take care to avoid accidental self-administration – seek medical attention should any specific signs be noticed. Advice to medical practitioners: In case 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.

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 two to five weeks after treatment.

3.6 Adverse events

Cattle, Sheep and Pigs:

None known.

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, lactation and fertility:
May be used in pregnant cows and ewes. The product is indicated for use in breeding and lactating sows and in breeding boars.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use (cattle).
Intramuscular use (sheep and pigs).

For the treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, lice and mange mites in cattle, and gastrointestinal roundworms and nasal bots in sheep, a single treatment of 1 ml (10 mg Doramectin) per 50 kg bodyweight, equivalent to 200 mcg/kg bodyweight, administered in the region of the neck by subcutaneous injection in cattle and by intramuscular injection in sheep.
For the treatment of clinical signs of *Psoroptes ovis* (sheep scab) and elimination of living mites on sheep a single treatment of 1 ml per 33 kg bodyweight, equivalent to 300 mcg/kg bodyweight, administered in the neck by intramuscular injection. In addition, adequate bio-security measures should be implemented to prevent re-infestation. It is important to ensure that all sheep which have been in contact with infested sheep are treated.

For the treatment of *Sarcoptes scabei* and gastrointestinal roundworms, lungworms, kidney worms and sucking lice in pigs, a single treatment of 1 ml per 33 kg bodyweight, equivalent to 300 mcg/kg bodyweight, administered by intramuscular injection.

Piglets weighing 16 kg or less should be dosed in accordance with the following table:

Body weight (kg)	**Dose (ml)**
Less than 4 kg	0.1 ml
5 - 7 kg	0.2 ml
8 - 10 kg	0.3 ml
11 - 13 kg	0.4 ml
14 - 16 kg	0.5 ml

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.

Maximum injection volume for each target species:
Cattle: 5 ml per injection site
Sheep: 1.5 ml per injection site
Pigs: 2.5 ml per injection site

The product may be used with automatic injection equipment with a vented draw-off system. When using an automatic device, vial stoppers must not be broached more than one time. For manual vial broachings, vial stoppers must not be broached more than 10 times for the 50 ml pack and not more than 25 times for the 250 ml and 500 ml packs.

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

In cattle, sheep and pigs overdoses up to 25, 10 and 10 times the maximum label recommended dose, respectively, resulted in no adverse clinical signs.

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

CATTLE:
Meat and offal: 70 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.

SHEEP:
Meat and offal: 70 days.
Not authorised for use in 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.

PIGS:
Meat and offal: 77 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP 54AA03.

4.2 Pharmacodynamics

Doramectin is an antiparasitic agent, isolated from fermentation of selected strains derived from the soil organism *Streptomyces avermitilis*. It is a macrocyclic lactone and is closely related to ivermectin. Both compounds share a wide spectrum of antiparasitic activity and produce a similar paralysis in roundworms and parasitic arthropods. Macrocyclic lactones activate glutamate gated chloride channels (GluCl) found on muscle membranes of the pharynx and particular neurones of invertebrate parasites. Entry of chloride ions into roundworm excitatory motor neurons or arthropod muscle cells results in hyperpolarization and elimination of the transmission signal which results in paralysis. The selective toxicity of the macrocyclic lactones as antiparasitics is attributed to this action on channels that are not present in the host animal. There is evidence that the membranes of the muscle cells of the invertebrate female reproductive tract may be more sensitive to macrocyclic lactones than receptors on nerve or other muscle and this may explain the dramatic but temporary reduction in egg production in parasites not killed or eliminated by drug therapy.

4.3 Pharmacokinetics

Maximum plasma concentration of doramectin occurs in 3 days with an elimination half-life of around 6 days in cattle, following subcutaneous administration.
Maximum plasma concentration of doramectin occurs in 2 days with an elimination half-life of 4.5 days in sheep, following intramuscular administration.

Maximum plasma concentration of doramectin occurs in 3 days with an elimination half-life of around 6 days in pigs, following intramuscular administration.

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

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in the original package in order to protect from light.

5.4 Nature and composition of immediate packaging

Type II amber glass multi-dose vials, with chlorobutyl rubber stoppers secured with an aluminium cap.

Package sizes:
Cardboard box containing 1 vial of 50 ml.
Cardboard box containing 1 vial of 250 ml.
Cardboard box containing 1 vial of 500 ml.

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 or used container should not enter water courses as doramectin may be 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

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

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

Cardboard box (50 ml, 250 ml, 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 10 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Doramectin 10 mg/ml

3. PACKAGE SIZE

50 ml.
250 ml.
500 ml.

4. TARGET SPECIES

Cattle, Sheep and Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use (cattle).
Intramuscular use (sheep and pigs).

7. WITHDRAWAL PERIODS

Withdrawal periods:

CATTLE:
Meat and offal: 70 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.

SHEEP:
Meat and offal: 70 days.
Not authorised for use in 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.

PIGS:
Meat and offal: 77 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.

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

Glass vial (250 ml, 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax 10 mg/ml Solution for Injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Doramectin 10 mg/ml.

3. TARGET SPECIES

Cattle, Sheep and Pigs.

4. ROUTES OF ADMINISTRATION

Subcutaneous use (cattle).
Intramuscular use (sheep and pigs).

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

CATTLE:
Meat and offal: 70 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.

SHEEP:
Meat and offal: 70 days.
Not authorised for use in 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.

PIGS:
Meat and offal: 77 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doramax. 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Doramectin 10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Doramax 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs.

2. Composition

Each ml contains:

Active substance:
Doramectin 10.0 mg

Excipients:
Butylhydroxyanisole (E320) 0.1 mg

Clear, yellowish solution.

3. Target species

Cattle, Sheep and Pigs.

4. Indications for use

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

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

Lungworms: (adults and fourth stage larvae)
Dictyocaulus viviparus

Eyeworms: (adults only)
Thelazia spp.

Warbles: (parasitic stages)
Hypoderma bovis
H.lineatum

Sucking lice:
Haematopinus eurysternus
Linognathus vituli
Solenopotes capillatus

Mange mites:
Psoroptes bovis
Sarcoptes scabiei

The product may also be used as an aid in the treatment of *Nematodirus helvetianus*, biting lice (*Damalinia bovis*), the tick *Ixodes ricinus* and the mange mite *Chorioptes bovis*.
Following product administration, efficacy against re-infection with the following parasites persists for the period indicated:

Species	**Days**
Bunostomum phlebotomum	22
Cooperia oncophora	21
Dictyocaulus viviparous	35
Haemonchus placei (adults only)	28
Linognathus vituli	28
Oesophagostomum radiatum	21
Ostertagia ostertagi	35
Psoroptes bovis	42
Trichostrongylus axei	28

SHEEP:
For treatment of gastrointestinal roundworms, lungworms, nasal bots and mange mites.

Gastrointestinal roundworms (adults and fourth stage larvae (L4) unless otherwise indicated):
Bunostomum trigonocephalum (adults only)
Chabertia ovina
Cooperia curticei (L4 only)
C.oncophora
Gaigeria pachyscelis
Haemonchus contortus
Nematodirus battus (L4 only)
N.filicollis (adults only)
N.spathiger
*Ostertagia (Teladorsagia) circumcincta**
Ostertagia (Teladorsagia) trifurcata (adults only)
Oesophagostomum venulosum (adults only)
O.columbianum
Strongyloides papillosus
Trichostrongylus axei
T.colubriformis
T.vitrinus
Trichuris spp. (adults only)

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

Lungworms (adults and fourth stage larvae (L4))
Cystocaulus ocreatus (adults only)
Dictyocaulus filaria
Muellerius capillaris (adults only)
Neostrongylus linearis (adults only)
Protostrongylus rufescens (adults only)

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

Mange mites
Psoroptes ovis

PIGS:
For treatment of gastrointestinal roundworms, lungworms, kidney worms, sucking lice and mange mites, in pigs.

Gastrointestinal roundworms (adults and fourth stage larvae)
Hyostrongylus rubidus
Ascaris suum
Strongyloides ransomi (adults only)
Oesophagostomum dentatum
Oesophagostomum quadrispinulatum

Lungworms
Metastrongylus spp. (adults only)

Kidney worms
Stephanurus dentatus (adults only)

Sucking Lice
Haematopinus suis

Mange Mites
Sarcoptes scabiei

The product protects pigs against infection or reinfection with *Sarcoptes scabiei* for 18 days.

5. Contraindications

Do not use in dogs, as severe adverse reactions may occur. In common with other avermectins, certain breeds of dog, such as collies, are especially sensitive to doramectin and particular care should be taken to avoid accidental consumption of the product.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

6. Special warnings

Special warnings:

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.

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.

Resistance to avermectins has been reported in *Teladorsagia spp* and *Haemonchus contortus* in sheep and in *Cooperia spp*. and *Ostertagia ostertagi* in cattle within the EU. A rise in the frequency of resistance of *Haemonchus spp* in cattle to ivermectin has been reported outside the EU. Resistance to macrocyclic lactones has been reported in *Psoroptes ovis*. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of roundworms and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:
When treating groups of animals, use a suitable automatic dosing device and vented draw-off apparatus.
For treatment of individual pigs, the use of appropriate sized needles and disposable syringes should be advised by a veterinarian. For the treatment of piglets weighing 16 kg or less, a 1 ml disposable syringe graduated in increments of 0.1 ml or less should be used.
Use sterile equipment and follow aseptic procedures. Avoid the introduction of contamination. Vial stoppers must not be broached more than one time. Swab the septum before removing each dose.
To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in 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 site.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke or eat while handling the product. Wash hands after use.
Take care to avoid accidental self-administration – seek medical attention should any specific signs be noticed. Advice to medical practitioners: In case 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.

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

Pregnancy and lactation:
May be used in pregnant cows and ewes. The product is indicated for use in breeding and lactating sows and in breeding boars.

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

Overdose:
In cattle, sheep and pigs overdoses up to 25, 10 and 10 times the maximum label recommended dose, respectively, resulted in no adverse clinical signs.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle, Sheep and Pigs:

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 or 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, routes and method of administration

Subcutaneous use (cattle).
Intramuscular use (sheep and pigs).

For the treatment of gastrointestinal roundworms, lungworms, eyeworms, warbles, lice and mange mites in cattle, and gastrointestinal roundworms and nasal bots in sheep, a single treatment of 1 ml (10 mg Doramectin) per 50 kg bodyweight, equivalent to 200 mcg/kg bodyweight, administered in the region of the neck by subcutaneous injection in cattle and by intramuscular injection in sheep.
For the treatment of clinical signs of *Psoroptes ovis* (sheep scab) and elimination of living mites on sheep a single treatment of 1 ml per 33 kg bodyweight, equivalent to 300 mcg/kg bodyweight, administered in the neck by intramuscular injection. In addition, adequate bio-security measures should be implemented to prevent re-infestation. It is important to ensure that all sheep which have been in contact with infested sheep are treated.

For the treatment of *Sarcoptes scabei* and gastrointestinal roundworms, lungworms, kidney worms and sucking lice in pigs, a single treatment of 1 ml per 33 kg bodyweight, equivalent to 300 mcg/kg bodyweight, administered by intramuscular injection.

Piglets weighing 16 kg or less should be dosed in accordance with the following table:

Body weight (kg)	**Dose (ml)**
Less than 4 kg	0.1 ml
5 - 7 kg	0.2 ml
8 - 10 kg	0.3 ml
11 - 13 kg	0.4 ml
14 - 16 kg	0.5 ml

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.

Maximum injection volume for each target species:
Cattle: 5 ml per injection site.
Sheep: 1.5 ml per injection site.
Pigs: 2.5 ml per injection site.

9. Advice on correct administration

The product may be used with automatic injection equipment with a vented draw-off system. When using an automatic device, vial stoppers must not be broached more than one time. For manual vial broachings, vial stoppers must not be broached more than 10 times for the 50 ml pack and not more than 25 times for the 250 ml and 500 ml packs.

10. Withdrawal periods

CATTLE:
Meat and offal: 70 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.

SHEEP:
Meat and offal: 70 days.
Not authorised for use in 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.

PIGS:
Meat and offal: 77 days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in the original package in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days

12. Special precautions for disposal

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

This veterinary medicinal product, or used container, should not enter water courses as doramectin may be 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

Package sizes: 50 ml, 250 ml and 500 ml multidose vials.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}
{DD/MM/YYYY}

{DD month 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 reactions:

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information

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.