[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taurador 10 mg/ml Solution for Injection for cattle, sheep & pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Doramectin 10.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethyl oleate	
Sesame oil, refined	
Butylhydroxyanisole (E320)	0.026 mg
Butylhydroxytoluene (E321)	0.01 mg

Clear, colourless to yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, Sheep and Pigs.

3.2 Indications for use for each target species

Cattle:
For the treatment of gastrointestinal roundworms, lungworms, warbles, lice, mange mites and eyeworms, listed below:

Gastrointestinal roundworms
Ostertagia ostertagi (L4, *inhibited larvae* and adult), *O. lyrata* (adult), *Haemonchus placei* (L4, adult), *Trichostrongylus axei* (L4, adult), *T. colubriformis* (L4, adult), *T. longispicularis* (adult), *Cooperia oncophora* (L4, adult), *C. pectinata* (adult), *C. punctata* (L4, adult), *C. surnabada* (*syn. mcmasteri*) (L4, adult), *Nematodirus spathiger* (adult), *Bunostomum phlebotomum* (adult), *Strongyloides papillosus* (adult), *Oesophagostomum radiatum* (L4, adult), *Trichuris* spp. (adult)

Lungworms
Dictyocaulus viviparous (L4, adult)

Eyeworms
Thelazia spp. (adult)

Warbles (parasitic stages)
Hypoderma bovis, H. lineatum

Sucking lice
Haematopinus eurysternus, Linognathus vituli, Solenopotes capillatus

Mange mites
Psoroptes bovis, Sarcoptes scabiei

The veterinary medicinal product also helps to treat:

Gastrointestinal roundworms
Nematodirus helvetianus

Mange mites
Chorioptes bovis

Biting lice
Damalinia bovis

The veterinary medicinal product also helps to combat:

Ticks
Ixodes ricinus

Persistent activity
The veterinary medicinal product protects cattle against infections or re-infections due to the below listed parasites during the indicated periods:

Species		Prolonged activity
Ostertagia ostertagi	:	28 days
Cooperia oncophora	:	21 days
Dictyocaulus viviparus	:	35 days
Linognathus vituli	:	28 days
Psoroptes bovis	:	42 days

Sheep:
For the treatment of gastrointestinal roundworms, lungworms, mange mites and nasal bots listed below:

Gastrointestinal roundworms (adult, L4 larvae and L3 larvae, unless stated otherwise):
Bunostomum trigonocephalum (adult), *Chabertia ovina, Cooperia curticei* (L4 larvae), *C. oncophora* (adult, L4 larvae), *Gaigeria pachycelis, Haemonchus contortus, Nematodirus filicollis* (adult), *N. battus* (L4 larvae), *N. spathiger, Ostertagia (Teladorsagia) circumcincta, Ostertagia (Teladorsagia) trifurcata* (adult), *Oesophagostomum venulosum* (adult), *Oesophagostomum columbianum, Strongyloides papillosus, Trichostrongylus axei* (adult, L4 larvae), *Trichostrongylus colubriformis, Trichostrongylus vitrinus* (adult, L4 larvae), *Trichuris* spp. (adult)

Lungworms (adults, L4 larvae and L3 larvae, unless stated otherwise):
Cystocaulus ocreatus (adult), *Dictyocaulus filaria*, *Muellerius capillaris* (adult), *Neostrongylus linearis* (adult), *Protostrongylus rufescens* (adult)

Nasal bots (L1, L2 and L3 larvae)
Oestrus ovis

Mange mites
Psoroptes ovis

Pigs:
For the 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 var. suis

The veterinary medicinal 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 dogs, such as collies, and also tortoises, are especially sensitive to doramectin and particular care should be taken to avoid accidental consumption of the veterinary medicinal product.

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

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each herd/flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd/flock, maintenance of susceptible refugia is essential to reduce that risk. Systemically applied interval-based treatment and treatment of the whole herd/flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd/flock should be sought from the responsible veterinarian.

Resistance to doramectin and other avermectins has been reported in *Psoroptes ovis* in cattle and sheep and in gastro-intestinal nematodes, especially *T. longispicularis*, *Haemonchus* spp., *Cooperia* spp. and *Ostertagia ostertagi* in cattle and *Teladorsagia* spp., *Trichostrongylus* spp. and *Haemonchus* spp. in sheep.

The veterinary medicinal product can be used for the treatment of *Ostertagia (Teladorsagia) circumcincta* in sheep, including the inhibited L4 larval stages, especially strains resistant to benzimidazoles.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of

suspected resistance using an appropriate diagnostic method (*e.g.* FECRT). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

Special precautions for safe use in the target species:
To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in 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 site. Consult your veterinary surgeon on the correct timing of this treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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.
This veterinary medicinal product can be irritating to eyes. Avoid accidental contact with the eyes, including hand-to eye contact. In the case of accidental contact with the eyes rinse with plenty of water.
The veterinary medicinal product may cause embryotoxicity and toxic effects to newborns via breastfeeding. Pregnant and breastfeeding woman should therefore take special care when handling this veterinary medicinal product.
Wash hands after use.

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).

The risk to aquatic ecosystems will be reduced by keeping treated animals away from water bodies for two to five weeks after treatment.

3.6 Adverse events

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 and lactation:
Cattle and Sheep:
May be used in pregnant cows and ewes.

Pigs:
Can be used in lactating sows.

Fertility:
Pigs:
Can be used in breeding 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 pig).

Cattle
A single treatment of 1 ml (10 mg doramectin) per 50 kg bodyweight, equivalent to 200 µg/kg bodyweight, administered in the region of the neck by subcutaneous injection.

Treatment schedule in regions where hypodermosis occurs
Cattle with hypodermosis should be treated at the end of the period of warble fly activity and before the larvae reach their resting site.

Sheep
A single treatment of 1 ml (10 mg doramectin) per 50 kg bodyweight, equivalent to 200 µg/kg bodyweight, administered by intramuscular injection in the neck region.

Pigs
A single treatment of 0.3 ml (3 mg doramectin) per 10 kg bodyweight (1.0 ml per 33.0 kg) corresponding to 300 µg/kg bodyweight, administered by intramuscular injection.

Piglets weighing 16 kg or less should be treated according to the following table:

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

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonable homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.
When treating groups of animals, use a suitable automatic dosing device and vented draw-off apparatus. Accuracy of the dosing device should be thoroughly checked.

For treatment of individual sheep or pigs, the use of appropriately sized needles and disposable syringes should be advised by a veterinarian. For the treatment of young lambs or piglets weighing 16kg or less, a 1mL disposable syringe graduated in increments of 0.1mL or less should be used.

Use dry, sterile equipment and follow aseptic procedures. Avoid introduction of contamination. Vial stoppers must not be broached more than 40 times with a 16G needle. Swab the septum before removing each dose.

Under cold conditions the veterinary medicinal product may be warmed to room temperature in a warm environment, to aid syringeability.

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

Overdoses of up to 25 times the recommended dose in cattle, up to 15 times in sheep and up to 10 times in pigs have produced no particular 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

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: QP54AA03

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 nematodes 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. Several resistance mechanisms to macrocyclic lactones have been proposed, for example polymorphisms or changes in expression of the GluCls target and transport protein genes, and to the increased expression of encoding drug-metabolizing enzymes. In addition, decreased expression of drug target genes may lead to a reduction of drug-binding sites and thus reduced drug effectiveness.

4.3 Pharmacokinetics

In cattle, maximum plasma concentration of Doramectin occurs 3 days after subcutaneous administration. The elimination half-life is around 6 days,

In sheep, maximum plasma concentration of Doramectin occurs 2 days after intramuscular administration. The elimination half-life is 4.5 days in sheep,

In pigs, maximum plasma concentration of Doramectin occurs 3 days after intramuscular administration of the veterinary medicinal product. The elimination half-life is around 6 days.

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. Doramectin is very persistent in soils.

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: 2 years
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

Store in the original package.

5.4 Nature and composition of immediate packaging

Multi-dose amber glass vials (Type II) closed a with a nitrile rubber stopper and sealed with an aluminium cap in a protective plastic container.

Package Sizes:
Protective plastic container with 1 x 100 ml vial.
Protective plastic container with 1 x 250 ml vial.
Protective plastic container with 1 x 500 ml vial.

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

Norbrook Laboratories (Ireland) Limited

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

Protective Plastic Container (100 ml, 250 ml, 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taurador 10 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Doramectin	10.0 mg

3. PACKAGE SIZE

100 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 pig).

7. WITHDRAWAL PERIODS

Withdrawal period:
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.
Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package.

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

Norbrook Laboratories (Ireland) Limited

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label (100 ml, 250 ml, 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Taurador 10 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Doramectin 10.0 mg

3. TARGET SPECIES

Cattle, Sheep and Pigs.

4. ROUTES OF ADMINISTRATION

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

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
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.
Once broached use by …

7. SPECIAL STORAGE PRECAUTIONS

Store in the original package.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Taurador 10 mg/ml Solution for Injection for cattle, sheep & pigs

2. Composition

Each ml contains:

Active Substance:

Doramectin	10.0 mg

Excipients:

Butylhydroxyanisole (E320)	0.026 mg
Butylhydroxytoluene (E321)	0.01 mg

Clear, colourless to yellow solution.

3. Target species

Cattle, Sheep and Pigs.

4. Indications for use

Cattle:
For the treatment of gastrointestinal roundworms, lungworms, warbles, lice, mange mites and eyeworms, listed below:

Gastrointestinal roundworms
Ostertagia ostertagi (L4, *inhibited larvae* and adult), *O. lyrata* (adult), *Haemonchus placei* (L4, adult), *Trichostrongylus axei* (L4, adult), *T. colubriformis* (L4, adult), *T. longispicularis* (adult), *Cooperia oncophora* (L4, adult), *C. pectinata* (adult), *C. punctata* (L4, adult), *C. surnabada* (*syn. mcmasteri*) (L4, adult), *Nematodirus spathiger* (adult), *Bunostomum phlebotomum* (adult), *Strongyloides papillosus* (adult), *Oesophagostomum radiatum* (L4, adult), *Trichuris* spp. (adult)

Lungworms
Dictyocaulus viviparous (L4, adult)

Eyeworms
Thelazia spp. (adult)

Warbles (parasitic stages)
Hypoderma bovis, H. lineatum

Sucking lice
Haematopinus eurysternus, Linognathus vituli, Solenopotes capillatus

Mange mites
Psoroptes bovis, Sarcoptes scabiei

The veterinary medicinal product also helps to treat:

Gastrointestinal roundworms

Nematodirus helvetianus

Mange mites
Chorioptes bovis

Biting lice
Damalinia bovis

The veterinary medicinal product also helps to combat:

Ticks
Ixodes ricinus

Persistent activity
The veterinary medicinal product protects cattle against infections or re-infections due to the below listed parasites during the indicated periods:

Species		Prolonged activity
Ostertagia ostertagi	:	28 days
Cooperia oncophora	:	21 days
Dictyocaulus viviparus	:	35 days
Linognathus vituli	:	28 days
Psoroptes bovis	:	42 days

Sheep:
For the treatment of gastrointestinal roundworms, lungworms, mange mites and nasal bots listed below:

Gastrointestinal roundworms (adult, L4 larvae and L3 larvae, unless stated otherwise):
Bunostomum trigonocephalum (adult), *Chabertia ovina, Cooperia curticei* (L4 larvae), *C. oncophora* (adult, L4 larvae), *Gaigeria pachycelis, Haemonchus contortus, Nematodirus filicollis* (adult), *N. battus* (L4 larvae), *N. spathiger, Ostertagia (Teladorsagia) circumcincta, Ostertagia (Teladorsagia) trifurcata* (adult), *Oesophagostomum venulosum* (adult), *Oesophagostomum columbianum, Strongyloides papillosus, Trichostrongylus axei* (adult, L4 larvae), *Trichostrongylus colubriformis, Trichostrongylus vitrinus* (adult, L4 larvae), *Trichuris* spp. (adult)

Lungworms (adults, L4 larvae and L3 larvae, unless stated otherwise):
Cystocaulus ocreatus (adult), *Dictyocaulus filaria*, *Muellerius capillaris* (adult), *Neostrongylus linearis* (adult), *Protostrongylus rufescens* (adult)

Nasal bots (L1, L2 and L3 larvae)
Oestrus ovis

Mange mites
Psoroptes ovis

Pigs:
For the 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 var. suis

The veterinary medicinal 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 dogs, such as collies, and also tortoises, are especially sensitive to doramectin and particular care should be taken to avoid accidental consumption of the veterinary medicinal product.

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

6. Special warnings

Special warnings:
Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each herd/flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd/flock, maintenance of susceptible refugia is essential to reduce that risk. Systemically applied interval-based treatment and treatment of the whole herd/flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd/flock should be sought from the responsible veterinarian.

Resistance to doramectin and other avermectins has been reported in *Psoroptes ovis* in cattle and sheep and in gastro-intestinal nematodes, especially *T. longispicularis*, *Haemonchus* spp., *Cooperia* spp. and *Ostertagia ostertagi* in cattle and *Teladorsagia* spp., *Trichostrongylus* spp. and *Haemonchus* spp. in sheep.

The veterinary medicinal product can be used for the treatment of *Ostertagia (Teladorsagia) circumcincta* in sheep, including the inhibited L4 larval stages, especially strains resistant to benzimidazoles.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available. It is recommended to investigate cases of suspected resistance using an appropriate diagnostic method (*e.g.* FECRT). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Special precautions for safe use in the target species:
To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in 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 site. Consult your veterinary surgeon on the correct timing of this treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Read package insert before 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.
This veterinary medicinal product can be irritating to eyes. Avoid accidental contact with the eyes, including hand-to eye contact. In the case of accidental contact with the eyes rinse with plenty of water.
The veterinary medicinal product may cause embryotoxicity and toxic effects to newborns via breastfeeding. Pregnant and breastfeeding woman should therefore take special care when handling this veterinary medicinal product.
Wash hands after use.

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).

The risk to aquatic ecosystems will be reduced by keeping treated animals away from water bodies for two to five weeks after treatment.

Pregnancy and lactation:
Cattle and Sheep:
May be used in pregnant cows and ewes.

Pigs:
Can be used in lactating sows.

Fertility:
Pigs:
Can be used in breeding sows and in breeding boars.

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

Overdose:
Overdoses of up to 25 times the recommended dose in cattle, up to 15 times in sheep and up to 10 times in pigs have produced no particular clinical signs that could be attributed to treatment with doramectin.

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

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 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.

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

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

Cattle
A single treatment of 1 ml (10 mg doramectin) per 50 kg bodyweight, equivalent to 200 µg/kg bodyweight, administered in the region of the neck by subcutaneous injection.

Treatment schedule in regions where hypodermosis occurs
Cattle with hypodermosis should be treated at the end of the period of warble fly activity and before the larvae reach their resting site.

Sheep
A single treatment of 1 ml (10 mg doramectin) per 50 kg bodyweight, equivalent to 200 µg/kg bodyweight, administered by intramuscular injection in the neck region.

Pigs
A single treatment of 0.3 ml (3 mg doramectin) per 10 kg bodyweight (1.0 ml per 33.0 kg) corresponding to 300 µg/kg bodyweight, administered by intramuscular injection.

Piglets weighing 16 kg or less should be treated according to the following table:

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

9. Advice on correct administration

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonable homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.
When treating groups of animals, use a suitable automatic dosing device and vented draw-off apparatus. Accuracy of the dosing device should be checked.

For treatment of individual sheep or pigs, the use of appropriately sized needles and disposable syringes should be advised by a veterinarian. For the treatment of young lambs or piglets weighing 16kg or less, a 1mL disposable syringe graduated in increments of 0.1mL or less should be used.

Use dry, sterile equipment and follow aseptic procedures. Avoid introduction of contamination. Vial stoppers must not be broached more than 40 times with a 16G needle. Swab the septum before removing each dose.

Under cold conditions the veterinary medicinal product may be warmed to room temperature in a warm environment, to aid syringeability.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

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

Marketing Authorisation Number:

Multi-dose amber glass vials (Type II) closed with a nitrile rubber stopper and sealed with an aluminium cap in a protective plastic container.

Package Sizes:
Protective plastic container with 1 x 100 ml vial.
Protective plastic container with 1 x 250 ml vial.
Protective plastic container with 1 x 500 ml vial.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 contact details to report suspected adverse reactions:

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland
Email: phvdept@norbrook.co.uk
Tel: +44 (0)28 3026 4435

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

Norbrook Manufacturing Limited
Rossmore Industrial Estate
Monaghan
Ireland

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.
Doramectin is very toxic to aquatic organisms and may accumulate in sediments. Doramectin is very persistent in soils.