ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 10 mg/mlSolution for Injection [IE].
Paramectin 10 mg/ml Soluzione iniettabile per bovini e suini [IT].
PARAMECTIN INYECTABLE [ES].
Paramectin 10 mg/ml Solução Injectável para bovinos e suínos [PT].

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ivermectin 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol Formal
Polyethylene Glycol 200

A clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle (beef and non-lactating dairy cattle) and pigs.

3.2 Indications for use for each target species

Cattle
Treatment of infections by the following parasites:

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited *O ostertagi*), *Ostertagia lyrata, Haemonchus placei, Trichostrongylus axei,*
Trichostrongylus colubriformis, Cooperia oncophora, Cooperia punctata, Cooperia pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Nematodirus helvetianus (adult).

Lungworms (adult and fourth stage larvae): *Dictyocaulus viviparus.*

Warbles (parasitic stages):
Hypoderma bovis, Hypoderma lineatum.

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus.

Mange Mites:
Psoroptes bovis, Sarcoptes scabiei var *bovis.*

The veterinary medicinal product may also be used to reduce infection of the mange mite *Chorioptes bovis,* but complete elimination may not occur.

Pigs
Treatment of infections by the following parasites:

Gastrointestinal roundworms:
Ascaris suum (adults and fourth-stage larvae).
Hyostrongylus rubidus (adults and fourth-stage larvae).

Oesophagostomum spp. (adults and fourth-stage larvae).
Strongyloides ransomi (adults).

Lungworms:
Metastrongylus spp. (adults).

Lice:
Haematopinus suis.

Mange mites:
Sarcoptes scabiei var *suis.*

3.3 Contraindications

Do not use in dogs or cats as severe adverse reactions may occur.
The veterinary medicinal product is not for intravenous or intramuscular use.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

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 warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid under dosing animals should be grouped according to their body weight and dosed according to the heaviest animal in the group.
Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

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

Should any apparent growth or discolouration occur the veterinary medicinal product should be discarded.
Do not smoke or eat while handling the veterinary medicinal product.
Direct contact of the veterinary medicinal product with the skin should be avoided.
Wash hands after use.
Take care to avoid self-injection. Inadvertent self-injection may result in local irritation and/or pain at the injection site.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

The veterinary medicinal product has been formulated specifically for cattle and pigs. It should not be administered to other species as severe adverse reactions may occur. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

3.6 Adverse events

Target species: Cattle (beef and non-lactating dairy cattle).

Common	Injection site swelling[1]

(1 to 10 animals / 100 animals treated):	
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Discomfort

[1] These soft tissue swellings disappear without treatment.

Target species: Pigs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pain[1] Injection site swelling[1]

[1] Mild and transient. These reactions disappear without treatment.

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 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:

Can be used in beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

Can be used in sows at any stage of pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use.

For single administration only.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Cattle
Ivermectin should be administered at a dosage rate of 200 microgram per kg bodyweight (1 ml/50 kg). It should be injected subcutaneously in front of or behind the shoulder using aseptic technique. A sterile 17-gauge, half-inch needle is recommended. Use of a draw-off needle is recommended to avoid excess broaching of the stopper. No untreated cattle should be added to the pasture. Treated animals should be monitored according to good husbandry practices always.

Pigs
The veterinary medicinal product should be administered at a dosage rate of 300 microgram per kg bodyweight (1 ml/33 kg). It should be injected subcutaneously into the neck using aseptic technique. A sterile 17-gauge, half-inch needle is recommended. Exact dosing is important especially in pigs with low bodyweight, therefore a syringe capable of dosing in 0.1 ml steps should be used.
The treatment schedule should be based on the local epidemiological situation.

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

In the case of overdose a symptomatic treatment should be given. The symptoms of overdose can be trembling, convulsions and coma.
A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.
In cattle, a single dose of 4.0 mg ivermectin per kg (20 times the use level) given subcutaneously resulted in ataxia and depression.
No systemic or local signs of toxic effects were reported at 3 times the recommended dose in both species – cattle and pigs.

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: 49 days.

Not authorised for use in lactating cows producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Pigs
Meat and Offal: 18 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA01

4.1 Pharmacodynamics

Ivermectin is a macrocyclic lactone derivative and acts by inhibiting nerve impulses. It binds selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels.
The macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

4.2 Pharmacokinetics

After subcutaneous administration of the recommended dose of the veterinary medicinal product to cattle (200 µg/kg), the following parameters were observed: Cmax of 37 ng/ml and AUC of 7558 ng/ml.hr. After subcutaneous administration of the recommended dose of the veterinary medicinal product to pigs (300 µg/kg), the following parameters were observed: Cmax of 14 ng/ml, and AUC of 1887 ng/ml.hr. Ivermectin is only partially metabolised. In cattle, only about 1-2% is excreted in the urine; the remainder is excreted in the faeces, approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products. Biliary excretion, followed by elimination in faeces is probably the major route of ivermectin excretion in pigs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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

Do not store above 25 °C.
Protect from direct sunlight.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product will be supplied in 50 ml, 100 ml, 250 ml, 500 ml and 1 litre volumes, presented in high density polyethylene vials with bromobutyl bungs and aluminium caps.

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 ivermectin may be 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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 10 mg/ml solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ivermectin 10 mg

3. PACKAGE SIZE

50 ml,
100 ml,
250 ml,
500 ml,
1000 ml.

4. TARGET SPECIES

Cattle (beef and non-lactating dairy cattle) and pigs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

For single administration only.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Cattle:
The veterinary medicinal product should be given only by subcutaneous injection at the recommended dosage level of 1 ml per 50 kg bodyweight.

For example:

Bodyweight (kg)	Dose Volume (ml)	Doses per Pack				
		50 ml	100 ml	250 ml	500 ml	1000 ml
Up to 50	1	50	100	250	500	1000
51 - 100	2	25	50	125	250	500
101 - 150	3	16	33	83	166	333
151 - 200	4	12	25	62	125	250
201 - 250	5	10	20	50	100	200
251 - 300	6	8	16	41	83	166

Over 300 kg bodyweight give 1 ml per 50 kg bodyweight.

Pigs:
The veterinary medicinal product should be given only by subcutaneous injection in the neck at the recommended dosage level of 1 ml per 33 kg bodyweight. The use of a sterile 17 gauge x ½ inch needle is recommended. Exact dosing is important, especially in pigs with low bodyweight, therefore a syringe capable of dosing in 0.1ml steps should be used.

The table below indicates the recommended dose volumes for various bodyweights and the number of doses/pack. In pigs, especially those under 16 kg for which less than 0.5 ml of veterinary medicinal product is indicated, dosing accuracy is important. For piglets weighing less than 16 kg give at 0.1 ml/3 kg bodyweight.

Bodyweight (kg)	Dose Volume (ml)	Doses per Pack				
		50 ml	100 ml	250 ml	500 ml	1000 ml
16	0.5	100	200	500	1000	2000
33	1.0	50	100	250	500	1000
50	1.5	33	66	166	333	666
66	2.0	25	50	125	250	500
99	3.0	16	33	83	166	333
133	4.0	12	25	62	125	250
166	5.0	10	20	50	100	200
200	6.0	8	16	41	83	166

Over 200 kg bodyweight give 1.0 ml per 33 kg bodyweight.

7. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:
Meat and offal: 49 days.

Not authorised for use in lactating cows producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Pigs:
Meat and offal: 18 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Protect from direct sunlight.

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}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 10 mg/ml solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ivermectin 10 mg

3. TARGET SPECIES

Cattle (beef and non-lactating dairy cattle) and pigs.

4. ROUTES OF ADMINISTRATION

Solution for Injection.
Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:
Meat and offal: 49 days.
Not authorised for use in lactating cows producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Pigs:
Meat and offal: 18 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Protect from light.

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

Paramectin 10 mg/ml solution for injection.

2. Composition

Each ml contains:

Active substance:

Ivermectin 10 mg

A clear, colourless solution.

3. Target species

Cattle (beef and non-lactating dairy cattle) and pigs.

4. Indications for use

For the treatment of internal and external parasites of beef and non-lactating dairy cattle and for the treatment of gastrointestinal roundworms, lungworms, lice and mange mites of pigs.

Cattle:
Treatment of infections by the following parasites:

Gastrointestinal roundworms (adults and fourth stage larvae):
Ostertagia ostertagi (including inhibited *O ostertagi*), *Ostertagia lyrata, Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia oncophora, Cooperia punctata, Cooperia pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Nematodirus helvetianus* (adult).

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus.

Warbles (parasitic stages):
Hypoderma bovis, Hypoderma lineatum.

Sucking Lice:
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus.

Mange Mites:
Psoroptes bovis, Sarcoptes scabiei var *bovis.*

The veterinary medicinal product may also be used to reduce infection of the mange mite *Chorioptes bovis* in cattle, but complete elimination may not occur.

Pigs:
Treatment of infections by the following parasites:

Gastrointestinal roundworms:
Ascaris suum (adults and fourth-stage larvae).
Hyostrongylus rubidus (adults and fourth-stage larvae).
Oesophagostomum spp (adults and fourth-stage larvae).
Strongyloides ransomi (adults).

Lungworms:
Metastrongylus spp (adults).

Lice:

Haematopinus suis.

Mange mites:
Sarcoptes scabiei var suis.

5. Contraindications

This product is not for intravenous or intramuscular use.
Do not use in dogs or cats as severe adverse reactions may occur.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

None.

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 warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid under dosing animals should be grouped according to their body weight and dosed according to the heaviest animal in the group.
Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

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

Should any apparent growth or discolouration occur the veterinary medicinal product should be discarded.
Do not smoke or eat while handling the veterinary medicinal product.
Direct contact of the veterinary medicinal product with the skin should be avoided.
Wash hands after use.
Take care to avoid self-injection. Inadvertent self-injection may result in local irritation and/or pain at the injection site.

Pregnancy and lactation:

Can be used in beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.
Can be used in sows at any stage of pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

In the case of overdose a symptomatic treatment should be given. The symptoms of overdose can be trembling, convulsions and coma.
A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.
In cattle, a single dose of 4.0 mg ivermectin per kg (20 times the use level) given subcutaneously resulted in ataxia and depression.
No systemic or local signs of toxic effects were reported at 3 times the recommended dose in both species – cattle and pigs.

Major incompatibilities:

None known.

Other precautions:

The veterinary medicinal product has been formulated specifically for cattle and pigs. It should not be administered to other species as severe adverse reactions may occur. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

7. Adverse events

Target species: Cattle (beef and non-lactating dairy cattle).

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Discomfort

[1] These soft tissue swellings disappear without treatment.

Target species: Pigs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pain[1] Injection site swelling[1]

[1] Mild and transient. These reactions disappear without treatment.

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.

For single administration only.

Cattle:
Ivermectin should be administered at a dosage rate of 200 μg per kg bodyweight (1 ml per 50 kg). It should be injected subcutaneously in front of or behind the shoulder using aseptic technique. A sterile 17-gauge, half-inch needle is recommended. Use of a draw-off needle is recommended to avoid excess broaching of the stopper.

For example:

Bodyweight (kg)	**Dose Volume (ml)**
Up to 50	1
51 – 100	2
101 – 150	3
151 – 200	4
201 – 250	5
251 – 300	6

Over 300 kg bodyweight give 1 ml per 50 kg bodyweight.

Pigs:

The veterinary medicinal product should be administered at a dosage rate of 300 µg per kg bodyweight (1 ml per 33 kg bodyweight). It should be injected subcutaneously into the neck using aseptic technique. A sterile 17-gauge, half-inch needle is recommended. Exact dosing is important, especially in pigs with low bodyweight, therefore a syringe capable of dosing in 0.1 ml steps should be used.

Bodyweight (kg)	Dose Volume (ml)
16	0.5
33	1.0
50	1.5
66	2.0
99	3.0
133	4.0
166	5.0
200	6.0

Over 200 kg bodyweight give 1.0 ml per 33 kg bodyweight.

9. Advice on correct administration

Swab the septum before removing each dose.
Use a dry sterile needle and syringe.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The treatment schedule should be based on the local epidemiological situation and according to veterinary advice.

CATTLE:

Treat all animals in contact with each other to prevent cross-infection.

Warbles
The best time to treat is in late autumn or early winter, before the small migrating larvae have time to cause serious damage.

PIGS:

Note 1
For effective mange control, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities.

Note 2
Since louse eggs are unaffected by ivermectin and may take up to 3 weeks to hatch, complete elimination may not occur following a single injection.

10. Withdrawal periods

Cattle:
Meat and offal: 49 days.
Not authorised for use in lactating cows producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Pigs:
Meat and offal: 18 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Protect from direct sunlight.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. 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 ivermectin may be 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 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

Multidose vials 50 ml, 100 ml, 250 ml, 500 ml and 1 litre volumes.

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

Manufacturer responsible for batch release:
Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works
Newry, Co. Down
BT35 6JP

<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

For animal treatment only.