ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramectin 0.8 mg/ml Drench for Sheep [IE]
Baymec Solution Buvable Ovins [FR]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Ivermectin 0.8 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Polysorbate 80	
Sodium Dihydrogen Orthophosphate Dihydrate	
Disodium Hydrogen Orthophosphate Dihydrate	

N,N-dimethylacetamide	
Benzyl Alcohol (E1519)	0.03 ml
Purified Water	

A clear yellow pale liquid.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the treatment of the following gastrointestinal nematodes, lungworms and nasal bots of sheep.

Gastrointestinal roundworms (adult and fourth stage larvae):
Haemonchus contortus [adult, L4 and inhibited L4],
Ostertagia (Teladorsagia) circumcincta [adult, L4 and inhibited L4]
Trichostrongylus spp.
Cooperia curticei (adults)
Cooperia oncophora [adult and L4]
Nematodirus spp. including *N. battus*
Strongyloides papillosus
Oesophagostomum columbianum [adult and L4]
Oesophagostomum venulosum (adults)
Chabertia ovina (adults)
Inhibited larval stages and benzimidazole resistant strains of *H. contortus* and *Ostertagia circumcincta* are also controlled.

Lungworms (adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

3.3 Contraindications

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

3.4 Special warnings

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 devise (if any).

Suspected clincal 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 another pharmacological class and having a different mode of action should be used.

Resistance to ivermectin has been reported in *Haemonchus contortus* in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility 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:

The product has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.
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 and crosses, and also in turtles/tortoises).

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:

Do not smoke or eat while handling the product.
Wash hands after use.
During administration avoid contact with the eyes. Any spillage of the product into eyes should be washed immediately.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cough[1]

[1] Immediately after 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 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:

Do not treat sheep in lactation or pregnant sheep 28 days before parturition.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

The product should be given orally, on a single occasion, at the recommended dosage rate of 200 micrograms ivermectin per kg of bodyweight (1 ml per 4 kg bodyweight).
To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

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- or overdosing.

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

The product has been administered to sheep at twice the recommended dose rate with no adverse effects.

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

Meat and offal: 10 days.

Milk: Not authorised for use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA01

4.2 Pharmacodynamics

Ivermectin is a 22, 23-dihydro derivative of an avermectin (which is a fermentation product produced by *Streptomyces avermitilis*) and consists of 2 homologues: B1a and B1b. It is a highly effective parasiticide with nematocidal, insecticidal and acaricidal activity documented in a wide range of domesticated animals.
Ivermectin has been demonstrated to be efficacious against benzimidazole resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta*.
Avermectins interact with glutamate-gated chloride ion channels, to increase membrane permeability to chloride ions, causing irreversible neuromuscular blockade in nematodes, followed by paralysis and death.

4.3 Pharmacokinetics

After oral administration of the recommended dose of the product to sheep (200 μg per kg bodyweight), the following mean parameters were observed:
Cmax 5.99 ng/ml; AUC 227.1 ng/ml.h; Tmax 12 hours, T½ elimination 24 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

The product will be supplied in 1.0 L, 2.5 L, 5.0 L and 2 x 5.0 L high density polyethylene back-pack containers complete with polypropylene plastic screw caps, packed into an outer carton.

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

{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 0.8 mg/ml Drench for Sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ivermectin 0.8 mg

3. PACKAGE SIZE

1 L,
2.5 L,
5.0 L,
2 x 5 L

4. TARGET SPECIES

Sheep.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

The product should be given orally at the recommended dosage level of 1 ml per 4 kg bodyweight. To ensure a correct dosage, body weight should be determined as accurately as possible; The use of suitably calibrated measuring equipment is recommended. 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- or overdosing.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 10 days.

Milk: Not authorised for use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.

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 0.8 mg/ml Drench for Sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ivermectin 0.8 mg

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Oral use.

The product should be given orally at the recommended dosage level of 1 ml per 4 kg bodyweight. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended. 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- or overdosing.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 10 days.

Milk: Not authorised for use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25^{o}C.

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 0.8 mg/ml Drench for Sheep

2. Composition

Each ml contains:

Active substance:

Ivermectin	0.8 mg

Excipients:

Benzyl Alcohol (E1519)	0.03 ml

3. Target species

Sheep.

4. Indications for use

For the treatment of gastrointestinal nematodes, lungworms and nasal bots of sheep.

The product at the recommended dosage level of 200 µg Ivermectin per kg bodyweight effectively controls the following parasites of sheep:

Gastrointestinal worms (adult and immature):
Haemonchus contortus [Adult, L4 and Inhibited L4]
Ostertagia(Teladorsagia) circumcincta [Adult, L4 And Inhibited L4]
Trichostrongylus spp.
Cooperia curticei (adults)
Cooperia oncophora [adult and L4]
Nematodirus spp., including *N. battus*,
Strongyloides papillosus,
Oesophagostomum columbianum [adult and L4]
Oesophagostomum venulosum (adults)
adult *Chabertia ovina*.
Inhibited larval stages and benzimidazole resistant strains of *H. contortus* and *Ostertagia circumcincta* are also controlled.

Lungworms (adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

5. Contraindications

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

6. Special warnings

Special warnings:

Frequent and repeated use may lead to the development of resistance. It is important that the correct dose is given in order to minimise the risk of resistance.

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 devise (if any).

Suspected clincal 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 another pharmacological class and having a different mode of action should be used.

Resistance to ivermectin has been reported in *Haemonchus contortus* in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:

The product has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.
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 and crosses, and also in turtles/tortoises).

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:

Do not smoke or eat while handling the product.
Wash hands after use.
During administration avoid contact with the eyes. Any spillage of the product into eyes should be washed immediately.

Pregnancy and lactation:

Do not treat sheep in lactation or pregnant sheep 28 days before parturition.

Interaction with other medicinal products and other forms of interaction:

None known.

Major incompatibilities:

None known.

7. Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cough[1]

[1] Immediately after 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 using the contact details at the end of this leaflet, or via your national reporting system: www.hpra.ie.

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

Oral use.

The product should be given orally at the recommended dosage level of 1 ml per 4 kg bodyweight (200 micrograms per kg).
To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.
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- or overdosing.
Administer as an oral drench on a single occasion.

9. Advice on correct administration

During administration avoid contact with the eyes. Any spillage of the product into eyes should be washed immediately.

10. Withdrawal periods

Meat and offal: 10 days.

Milk: Not authorised for use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C.
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: 6 months.

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

The product will be supplied in 1 L, 2.5 L, 5.0 L and 2 x 5.0 L high density polyethylene back-pack containers complete with polypropylene plastic screw caps, packed into an outer carton.

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
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

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

17. Other information

POM (Prescription Only).

For animal treatment only.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Paramectin 0.8 mg/mL Drench for Sheep

2. Composition

Each ml contains:

Active substance:

Ivermectin	0.8 mg

Excipients:

Benzyl Alcohol (E1519)	0.03 ml

3. Target species

Sheep.

4. Indications for use

For the treatment of gastrointestinal nematodes, lungworms and nasal bots of sheep.

The product at the recommended dosage level of 200 µg Ivermectin per kg bodyweight effectively controls the following parasites of sheep:

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Trichostrongylus spp.
Cooperia curticei (adults)
Cooperia oncophora [adult and L4]
Nematodirus spp., including *N. battus*,
Strongyloides papillosus,
Oesophagostomum columbianum [adult and L4]
adult *Chabertia ovina*.
Inhibited larval stages and benzimidazole resistant strains of *H. contortus* and *Ostertagia circumcincta* are also controlled.

Lungworms (adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

5. Contraindications

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

6. Special warnings

Special warnings:

Frequent and repeated use may lead to the development of resistance. It is important that the correct dose is given in order to minimise the risk of resistance.

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 devise (if any).

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Resistance to ivermectin has been reported in *Haemonchus contortus* in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:

The product has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.
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 and crosses, and also in turtles/tortoises).

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:

Do not smoke or eat while handling the product.
Wash hands after use.
During administration avoid contact with the eyes. Any spillage of the product into eyes should be washed immediately.

Pregnancy and lactation:

Do not treat sheep in lactation or pregnant sheep 28 days before parturition.

Interaction with other medicinal products and other forms of interaction:

None known.

Major incompatibilities:

None known.
Overdose:

The product has been administered to sheep at twice the recommended dose rate with no adverse effects.

7. Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cough[1]

[1] Immediately after 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 using the contact details at the end of this leaflet, or via your national reporting system: www.hpra.ie.

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Oral use.

The product should be given orally at the recommended dosage level of 1 ml per 4 kg bodyweight (200 micrograms per kg).
To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.
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- or overdosing.
Administer as an oral drench on a single occasion.

9. Advice on correct administration

During administration avoid contact with the eyes. Any spillage of the product into eyes should be washed immediately.

10. Withdrawal periods

Meat and offal: 10 days.

Milk: Not authorised for use in lactating sheep producing milk for human consumption.

Sheep must not be treated within 60 days prior to the commencement of lactation if milk is to be used for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C.
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: 6 months.

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

The product will be supplied in 1 L, 2.5 L, 5.0 L and 2 x 5.0 L high density polyethylene back-pack containers complete with polypropylene plastic screw caps, packed into an outer carton.

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
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

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

17. Other information

POM (Prescription Only).

For animal treatment only.