ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Closamectin 5 mg/ml + 200 mg/ml Pour-On Solution for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Ivermectin	5 mg
Closantel (as closantel sodium)	200 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Brilliant Blue FCF (E133)	0.1 mg
Anhydrous Ethanol	
Macrogol	
Cetearyl Ethylhexanoate	
Isopropyl Myristate	
Povidone	
Denatonium Benzoate	
Trolamine	
Isopropyl Alcohol	

A clear blue/green solution.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle.

3.2 Indications for use for each target species

For the treatment of mixed trematode (fluke) and nematode or arthropod infestations due to roundworms, lungworms, eyeworms, warbles, mites and lice of cattle.

Gastrointestinal roundworms (adults and fourth stage larvae)
Ostertagia ostertagi (including inhibited *O. ostertagi*), *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adult), *Strongyloides papillosus* (adult).

Lungworms (adult and fourth stage larvae)
Dictyocaulus viviparus

Trematodes (adult and late immatures)
Fasciola gigantica
Fasciola hepatica
Treatment of fluke at 12 weeks (mature) >95% efficacy.

Treatment of fluke at 7 weeks (late immature) >95% efficacy.

Eyeworms (adult)
Thelazia spp

Cattle grubs (parasitic stages)
Hypoderma bovis, Hypoderma lineatum

Lice
Linognathus vituli, Haematopinus eurysternus, Damalinia bovis

Mange Mites
Chorioptes bovis, Sarcoptes scabiei var *bovis*

3.3 Contraindications

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

Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.

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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

The effect of rain on the pour-on formulation at the time of and after application has not been investigated. For maximum effect animals should be kept indoors or undercover following treatment when there is rain or an imminent risk of rain.

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 tests 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 *Ostertagia ostertagi* and *Cooperia* spp. in cattle. Therefore the use of this product should be based on local (regional, farm) epidemiological information about the susceptibility of these species 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:

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming (licking), all animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal

period. Non-compliance with this recommendation may lead to residues violations (see section 3.12) or in very rare cases, it can lead to adverse events (see section 3.6) in non-treated animals.

It is not advisable to administer the product when *Hypoderma lineatum* larvae are localised in the periaesophagic region, or when *Hypoderma bovis* larvae are situated in the spinal canal. Seek professional veterinary advice to determine the best period of use.

Care should be taken to ensure animals are not overdosed by the application volume, accidental spillage or oral ingestion, as overdosage may result in signs of toxicity such as inco-ordination and blindness. It is recommended that animals are not clipped prior to treatment to reduce the risk of increased drug absorption and hence bioavailability, or oral ingestion through mutual grooming.

Care should be taken when treating animals which may be of low nutritional status as this may increase susceptibility of adverse events occurring.

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

This product may be irritating to human skin and eyes or cause hypersensitivity. Avoid skin and/or eye contact with the product during treatment, when handling recently treated animals or when cleaning the used equipment. Personal protective clothing consisting of nitrile rubber gloves and boots with a waterproof coat should be worn when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

This product may be toxic after accidental ingestion. Avoid ingestion by hand-to-mouth contact. Do not eat, drink or smoke whilst handling the product. In case of accidental ingestion seek medical advice immediately and show the package leaflet to the physician. Wash hands after use.

This product is flammable. Keep away from sources of ignition. Use only in well ventilated areas or outdoors.

Special precautions for the protection of the environment:

The product is very toxic to aquatic organisms and dung insects.

Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment.

Long term effects on dung insects caused by continuous or repeated use cannot be excluded therefore repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

Other precautions:

Avermectins may not be well tolerated in 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/tortoises).

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neurological signs[1] (e.g. Ataxia, Blindness, Recumbency) Gastrointestinal signs (e.g. Anorexia, Diarrhoea) Death[2]

[1] When there is an adverse event in a herd, several animals may be affected. Should neurological signs be observed in one animal, it is recommended to reinforce surveillance, at the herd level, of all treated animals.
[2] In extreme cases.

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:
The veterinary medicinal product can be administered to cattle (including dairy, beef/suckler cattle) at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. See section 3.12.

3.8 Interactions with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

The veterinary medicinal product should be administered topically at a dosage rate of 500 µg ivermectin per kg bodyweight and 20 mg closantel per kg bodyweight (1 ml per 10 kg).

The formulation should be applied along the midline of the back in a narrow strip between the withers and the tail head.

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

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by a veterinary professional.

HANDY DOSING GUIDE		ANIMALS SHOULD BE WEIGHED AND GROUPED ACCORDING TO BODYWEIGHT TO AVOID UNDER OR OVER-DOSING*				
BODYWEIGHT	DOSE VOLUME	NUMBER OF FULL DOSES PER PACK				
		250 ml	500 ml	1 litre	2.5 litre	5 litre
100kg*	10 ml	25	50	100	250	500
150kg	15 ml	16	33	66	166	333
200kg	20 ml	12	25	50	125	250
250kg	25 ml	10	20	40	100	200
300kg	30 ml	8	16	33	83	166
350kg	35 ml	7	14	28	71	142
400kg	40 ml	6	12	25	62	125
450kg	45 ml	5	11	22	55	111

500kg	50 ml	5	10	20	50	100
550kg	55 ml	4	9	18	45	90
600kg	60 ml	4	8	16	41	83

* Dose rate 1 ml per 10 kg bodyweight

Avoid introduction of contamination.

If stored at temperatures below 0°C, the veterinary medicinal product may appear cloudy. Allowing to warm to room temperature will restore the normal appearance without affecting efficacy.

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

At doses of three times the recommended dose, no significant clinical signs were recorded. No antidote has been identified for ivermectin or closantel overdose. Symptomatic treatment may be beneficial.

Closantel like other salicylanilides is a potent uncoupler of oxidative phosphorylation and the safety index is not as high as is the case of many other anthelmintics. However where used as directed there are unlikely to be any untoward effects. Signs of overdosage can include slight loss of appetite, loose faeces, decreased vision and increased frequency of defecation. High doses may cause blindness, hyperventilation, general weakness and inco-ordination, hyperthermia, convulsions, tachycardia and in extreme cases death.

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: 58 days.

Not authorised for use in cattle producing milk for human consumption including during the dry period. Do not use during the second half of pregnancy in heifers which are intended to produce milk for human consumption.

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming (licking), all animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residues violations in non-treated animals.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet Code:
QP54AA51

4.2 Pharmacodynamics

Ivermectin is an endectocide with activity against a wide range of internal and external parasites. Ivermectin is a macrocylic lactone 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 macrocylic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

Closantel is a member of the salicylanilide class of anthelmintics. Salicylanilides are hydrogen (proton) ionophores (referred to as oxidative phosphorylase uncouplers.)

The chemical structure of salicylanilides illustrate the possession of a detachable proton. This type of molecule is lipophilic and is known to shuttle protons across membranes, in particular the inner mitochondrial membrane. Closantel acts by uncoupling oxidative phosphorylation.

Closantel is a parasiticide with flukicide activity and efficacy against certain other helminths and arthropods.

4.3 Pharmacokinetics

After topical administration of the veterinary medicinal product to cattle at a dose rate of 500 µg ivermectin per kg and 20 mg closantel per kg the following parameters were observed: Ivermectin – Cmax of 19.13 ng/mL and AUC of 2440 ng.hr/mL; Closantel – Cmax of 68.5 µg/mL and AUC of 35207 µg.hr/mL.

Ivermectin is only partially metabolised. In cattle, only about 1 to 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. Salicylanilides are poorly metabolised and are excreted mainly unchanged. About 90% of closantel is excreted unchanged in the faeces and urine in cattle.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

5.3 Special precautions for storage

Do not store above 25 °C.
Store upright in original container.
Protect from light.
Discard unused material.
Flammable – keep away from heat, sparks, open flame or other sources of ignition.

5.4 Nature and composition of immediate packaging

Translucent 250 ml, 500 ml and 1 L HDPE containers with white HDPE caps and integrated measuring device, packaged in cartons and white 1 L, 2.5 L and 5 L HDPE backpacks with white polypropylene screw caps, packaged in cartons.

A 4 L combination pack is also available containing 1 x 1 L and 1 x 2.5 L HDPE back pack and a 1 x 500 mL HDPE container with dosing gun.

Not all packs 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 product

The veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.

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

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

7. MARKETING AUTHORISATION NUMBER

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

Closamectin 5 mg/ml + 200 mg/ml Pour-On Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin	5 mg/ml
Closantel	200 mg/ml

3. PACKAGE SIZE

250 ml [500 ml, 1 L, 2.5 L, 4 L, 5 L]

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

HANDY DOSING GUIDE		ANIMALS SHOULD BE WEIGHED AND GROUPED ACCORDING TO BODYWEIGHT TO AVOID UNDER OR OVER-DOSING*				
BODYWEIGHT	DOSE VOLUME	NUMBER OF FULL DOSES PER PACK				
		250 mL	500 mL	1 litre	2.5 litre	5 litre
100 kg*	10 mL	25	50	100	250	500
150 kg	15 mL	16	33	66	166	333
200 kg	20 mL	12	25	50	125	250
250 kg	25 mL	10	20	40	100	200
300 kg	30 mL	8	16	33	83	166
350 kg	35 mL	7	14	28	71	142
400 kg	40 mL	6	12	25	62	125
450 kg	45 mL	5	11	22	55	111
500 kg	50 mL	5	10	20	50	100
550 kg	55 mL	4	9	18	45	90
600 kg	60 mL	4	8	16	41	83

* Dose rate 1 mL per 10 kg bodyweight

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 58 days.

Not authorised for use in cattle producing milk for human consumption including during the dry period. Do not use during the second half of pregnancy in heifers which are intended to produce milk for human consumption.

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming (licking), all animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residues violations in non-treated animals.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Store upright in original container.
Protect from light.
Flammable – keep away from heat, sparks, open flame or other sources of ignition.
Discard unused material.
Avoid introduction of contamination.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Closamectin 5 mg/ml + 200 mg/ml Pour-On Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin	5 mg/ml
Closantel	200 mg/ml

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Pour-on use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 58 days.

Not authorised for use in cattle producing milk for human consumption including during the dry period. Do not use during the second half of pregnancy in heifers which are intended to produce milk for human consumption.

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming (licking), all animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residues violations in non-treated animals.

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Protect from light.
Store upright in original container.
Discard unused material.
Flammable – keep away from heat, sparks, open flame or other sources of ignition.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Closamectin 5 mg/ml + 200 mg/ml Pour-On Solution for Cattle

2. Composition

Each ml contains:

Active substances:

Ivermectin	5 mg
Closantel	200 mg

Excipient:

Brilliant Blue FCF (E133)	0.1 mg

A clear blue/green solution.

3. Target species

Cattle.

4. Indications for use

For the treatment of mixed trematode (fluke) and nematode or arthropod infestations due to roundworms, lungworms, eyeworms, warbles, mite and lice of cattle.

Gastrointestinal roundworms (adults and fourth stage larvae)
Ostertagia ostertagi (including inhibited *O. ostertagi*), *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adult), *Strongyloides papillosus* (adult).

Lungworms (adult and fourth stage larvae)
Dictyocaulus viviparus

Trematodes (adult and late immatures)
Fasciola gigantica
Fasciola hepatica
Treatment of fluke at 12 weeks (mature) >95% efficacy.
Treatment of fluke at 7 weeks (late immature) >95% efficacy.

Eyeworms (adult)
Thelazia spp

Cattle grubs (parasitic stages)
Hypoderma bovis, Hypoderma lineatum

Lice
Linognathus vituli, Haematopinus eurysternus, Damalinia bovis

Mange Mites
Chorioptes bovis, Sarcoptes scabiei var *bovis*

5. Contraindications

Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.

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

6. Special warnings

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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

The effect of rain on the absorption of the pour on formulation at the time of and after application has not been investigated. For maximum effect animals should be kept indoors or undercover following treatment, when there is rain or an imminent risk of rain.

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 tests 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 *Ostertagia ostertagi* and *Cooperia* spp. in cattle. Therefore the use of this product should be based on local (regional, farm) epidemiological information about the susceptibility of these species and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming (licking), all animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residues violations (see section 10) or in very rare cases, it can lead to adverse events (see section 7) in non-treated animals.

It is not advisable to administer the product when *Hypoderma lineatum* larvae are localised in the periaesophagic region, or when *Hypoderma bovis* larvae are situated in the spinal canal. Seek professional veterinary advice to determine the best period of use.

Care should be taken to ensure animals are not overdosed by the application volume, accidental spillage or oral ingestion, as overdosage may result in signs of toxicity such as inco-ordination and blindness. It is recommended that animals are not clipped prior to treatment to reduce the risk of increased drug absorption and hence bioavailability, or oral ingestion through mutual grooming.

Care should be taken when treating animals which may be of low nutritional status as this may increase susceptibility of adverse events occurring.

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

This product may be irritating to human skin and eyes or cause hypersensitivity. Avoid skin and/or eye contact with the product during treatment, when handling recently treated animals or when cleaning the used equipment. Personal protective clothing consisting of nitrile rubber gloves and boots with a waterproof coat should be worn when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

This product may be toxic after accidental ingestion. Avoid ingestion by hand-to-mouth contact. Do not eat, drink or smoke whilst handling the product. In case of accidental ingestion seek medical advice immediately and show the package leaflet to the physician. Wash hands after use.

This product is flammable. Keep away from sources of ignition. Use only in well ventilated areas or outdoors.

Special precautions for the protection of the environment:

The product is very toxic to aquatic organisms and dung insects.

Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment.

Long term effects on dung insects caused by continuous or repeated use cannot be excluded therefore repeat treatments on a pasture within a season should only be given on the advice of a veterinarian."

Other precautions:

Avermectins may not be well tolerated in 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/tortoises).

Pregnancy and lactation:
The veterinary medicinal product can be administered to cattle (including dairy, beef/suckler cattle) at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. See section 'Withdrawal periods.'

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

Overdose:
At doses of three times the recommended dose, no significant clinical signs were recorded. No antidote has been identified for ivermectin or closantel overdose. Symptomatic treatment may be beneficial.

Closantel like other salicylanilides is a potent uncoupler of oxidative phosphorylation and the safety index is not as high as is the case of many other anthelmintics. However where used as directed there are unlikely to be any untoward effects. Signs of overdosage can include slight loss of appetite, loose faeces, decreased vision and increased frequency of defecation. High doses may cause blindness, hyperventilation, general weakness and inco-ordination, hyperthermia, convulsions, tachycardia and in extreme cases death.

7. Adverse reactions

Very rare (<1 animal / 10,000 animals treated, including	Neurological signs[1] (e.g. Ataxia (incoordination), Blindness, Recumbency)

isolated reports):	Gastrointestinal signs (e.g. Anorexia (loss of appetite), Diarrhoea) Death[2]

[1] When there is an adverse event in a herd, several animals may be affected. Should neurological signs be observed in one animal, it is recommended to reinforce surveillance, at the herd level, of all treated animals.
[2] In extreme cases.

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:

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

Pour on use. The veterinary medicinal product should be administered topically at a dosage rate of 500 µg ivermectin per kg bodyweight and 20 mg closantel per kg bodyweight (1 mL per 10 kg).

The formulation should be applied along the midline of the back in a narrow strip between the withers and the tail head.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by a veterinary professional.

9. Advice on correct administration

Assess bodyweight carefully prior to administration.
Avoid introduction of contamination.
If stored at temperatures below 0°C, the veterinary medicinal product may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

10. Withdrawal periods

Meat and offal: 58 days.

Not authorised for use in cattle producing milk for human consumption including during the dry period. Do not use during the second half of pregnancy in heifers which are intended to produce milk for human consumption.

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming (licking), all animals in a group should be treated at the same time and treated animals should be kept separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residues violations in non-treated animals.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Protect from light.
Store upright in original container.
Flammable – keep away from heat, sparks, open flame or other sources of ignition.

Do not use this veterinary medicinal product after the expiry date which is stated on label and carton after 'Exp'. The expiry date refers to the last day of that month.

12. Special precautions for disposal

The veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.

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

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

250 ml, 500 ml and 1 L containers, 1 L, 2.5 L and 5 L backpacks and 4 L combination pack with dosing gun.
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*).

(UK)

16. Contact details

(IE)
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

(UK)
Marketing authorisation holder and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited

Station Works
Newry
Co. Down
BT35 6JP
Northern 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

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

17. Other information

For animal treatment only.

European Patent No. EP1646425B