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

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Plus 10/100 mg/ml Solution for Injection for Cattle [UK(NI), DK, BE, PT, RO]
Bimectin Fluke 10/100 mg/ml Solution for Injection for Cattle [DE]
Mectaject D 10/100 mg/ml Solution injectable pour bovins [FR]
Renomec Plus 10/100 mg/ml Solucion inyectable para bovinos [ES]
Maximec Plus 10/100 mg/ml Solution for injection for Cattle [PL, IT]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Ivermectin 10mg
Clorsulon 100mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol formal
Propylene glycol
Monoethanolamine (for pH adjustment)

A clear colourless to pale yellow sterile non-aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of mixed trematode and nematode or arthropod infestations of the following parasites:

Gastrointestinal roundworms (adult and fourth-stage larvae):
Ostertagia ostertagi (including inhibited larval stages)
Ostertagia lyrata
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia oncophora
Cooperia punctata
Cooperia pectinata
Bunostomum phlebotomum
Oesophagostamum radiatum
Strongyloides papillosus (adult)
Nematodirus spathiger (adult)
Nematodirus helvetianus (adult)

Lungworms (adult and fourth-stage larvae)
Dictyocaulus viviparous

Liver fluke (adult):
Fasciola hepatica

Eye worms (adult):
Thelazia spp

Warbles (parasitic stages):
Hypoderma bovis
Hypoderma lineatum

Mange mites:
Psoroptes bovis
Sarcoptes scabiei var. *bovis*

Sucking lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus.

The veterinary medicinal product may also be used as an aid in the control of biting lice (*Damalinia bovis)* and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Persistent activity

The veterinary medicinal product given at the recommended dosage of 1 ml/50 kg bodyweight controls re-infection with *Haemonchus placei, Cooperia* spp. and *Trichostrongylus axei* acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

3.3 Contraindications

Do not use intramuscularly or intravenously.
This veterinary medicinal product is a low volume product authorised for use in cattle. It must not be used in other species as severe adverse reactions, including fatalities in dogs, may occur, especially Collies, Old English Sheepdogs and related breeds or crosses.
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 device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.
Resistance to Ivermectin has been reported in *Ostertagia ostertagi* and *Cooperia* species in cattle within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of these helminth 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:
This veterinary medicinal product does not contain any antimicrobial preservative. Swab septum before removing each dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke or eat whilst handling the veterinary medicinal product.
Wash hands after use.
Personal protective equipment consisting of gloves and glasses should be worn when handling the veterinary medicinal product. Direct contact with the skin should be avoided.
Take care to avoid self-injection: the product may cause local irritation and/or pain at the injection site. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Discomfort[1,2] Injection site swelling[2]

[1]Transitory.
[2]Resolves over time 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 its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used in pregnancy and lactation.

Fertility:
Can be used in breeding animals.

See section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use.

Dosage and duration of treatment

200 µg ivermectin and 2 mg clorsulon per kg bodyweight corresponding to a single dose of 1 ml per 50 kg bodyweight.

Method of administration

The veterinary medicinal product should be administered only by subcutaneous injection under the loose skin in front of or behind the shoulder.

Divide doses in excess of 10 ml between different injection sites and use different sites to those used for other parenteral medications.

A sterile 17 gauge ½ inch (15-20 mm) needle is recommended. Replace with a fresh sterile needle after every 10-12 animals or sooner if the needle becomes soiled.

When the temperature of the product is below 5°C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15°C will greatly increase the ease with which the product can be injected.

When using the 500 ml pack size use only automatic syringe equipment. For the 50 ml pack size, use of a multidose syringe is recommended.

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person.

To ensure a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

If animals are to be treated collectively rather than individually, to avoid under- or over-dosing, they should be grouped according to their bodyweight and dosed accordingly.

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

A dose of 25 ml product per 50 kg bodyweight (25 times the recommended dose level) may result in an injection site lesion, including tissue necrosis, oedema, fibrosis and inflammation. No other drug-related reactions have been observed.

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: 66 days
Milk: Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA51

4.2 Pharmacodynamics

Ivermectin is a member of the macrocyclic lactone class of endectocides and has a unique mode of action. It has broad and potent antiparasitic activity. 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 hyperpolarisation of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels such as those gated by the neurotransmitter gamma-amino-butyric 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, that the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

Clorsulon is rapidly absorbed in the blood stream. It is bound to the erythrocytes and plasma which are ingested by the fluke. Clorsulon inhibits the glycolytic enzymes in the fluke and deprives it of its main source of metabolic energy.

4.3 Pharmacokinetics

After subcutaneous administration of 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight, the plasma profile demonstrated a slow, steady absorption of ivermectin which reached a maximum plasma concentration at a median time of 1.50 days. In contrast, clorsulon appeared rapidly absorbed with a maximum plasma concentration at a median time of 0.25 days. The terminal half-life for the two active ingredients were determined as follows: Ivermectin approximately 3.79 days and Clorsulon approximately 3.58 days.

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

5.3 Special precautions for storage

Keep the container in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Container material: High density polyethylene
Container closure: Siliconised grey bromobutyl rubber stopper with tamper evident aluminium overseal.
Container colour: Natural
Container volume: 50 ml, 250 ml or 500 ml.
Cardboard box with 1 x 50 ml bottle.
Cardboard box with 1 x 250 ml bottle.
Cardboard box with 1 x 500 ml bottle.

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 is extremely dangerous for fish and other aquatic organisms.

Do not contaminate surface waters or ditches with the product or used container.

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

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton – 50 ml, 250 ml, 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Plus 10/100 mg/ml Solution for Injection [UK(NI), DK, BE, PT, RO]
Bimectin Fluke 10/100 mg/ml Solution for Injection [DE]
Mectaject D 10/100 mg/ml Solution injectable [FR]
Renomec Plus 10/100 mg/ml Solucion inyectable [ES]
Maximec Plus 10/100 mg/ml Solution for injection [PL, IT]

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 10 mg of ivermectin and 100 mg of clorsulon.

3. PACKAGE SIZE

50ml
250ml
500ml

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

Dosage: 1ml per 50 kg bodyweight by subcutaneous injection.

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 66 days.
Milk: Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

8. EXPIRY DATE

Exp.
Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label – 250 ml, 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Plus 10/100 mg/ml Solution for Injection [UK(NI), DK, BE, PT, RO]
Bimectin Fluke 10/100 mg/ml Solution for Injection [DE]
Mectaject D 10/100 mg/ml Solution injectable [FR]
Renomec Plus 10/100 mg/ml Solucion inyectable [ES]
Maximec Plus 10/100 mg/ml Solution for injection [PL, IT]

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 10 mg of ivermectin and 100 mg of clorsulon.

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.

Dosage: 1ml per 50 kg bodyweight by subcutaneous injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle (meat and offal): 66 days.
Milk: Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

6. EXPIRY DATE

Exp.
Once opened use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

9. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label – 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Plus [UK(NI), DK, BE, PT, RO]
Bimectin Fluke [DE]
Mectaject D [FR]
Renomec Plus [ES]
Maximec Plus [PL, IT]

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains 10 mg of ivermectin and 100 mg of Clorsulon.

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.
Once opened use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bimectin Plus 10/100 mg/ml Solution for Injection for Cattle [UK(NI), DK, BE, PT, RO]
Bimectin Fluke 10/100 mg/ml Solution for Injection for Cattle [DE]
Mectaject D 10/100 mg/ml Solution injectable pour bovins [FR]
Renomec Plus 10/100 mg/ml Solucion inyectable para bovinos [ES]
Maximec Plus 10/100 mg/ml Solution for injection for Cattle [PL, IT]

2. Composition

Each ml contains:

Active Substance(s)
Ivermectin 10 mg
Clorsulon 100 mg

A clear colourless to pale yellow sterile non-aqueous solution.

3. Target species

Cattle

4. Indications for use

For the treatment of mixed infestations of adult liver fluke and gastro-intestinal roundworms, lungworms, eye worms and/or warbles, mites and lice of cattle.

The veterinary medicinal product treats:

PARASITE	**Adult**	**L4**	**Inhibited L4**
Gastrointestinal roundworms			
Ostertagia ostertagi	+	+	+
Ostertagia lyrata	+	+	
Haemonchus placei	+	+	
Trichostrongylus axei	+	+	
Trichostrongylus colubriformis	+	+	
Cooperia oncophora	+	+	
Cooperia punctata	+	+	
Cooperia pectinata	+	+	
Bunostomum phlebotomum	+	+	
Oesophagostomum radiatum	+	+	
Strongyloides papillosus	+		
Nematodirus helvetianus	+		
Nematodirus spathiger	+		

PARASITE	**Adult**	**L4**	**Inhibited L4**
Lungworms			
Dictyocaulus viviparus	+	+	

Eye worms			
Thelazia spp.	+		

PARASITE	**Adult**	**Immature**
Liver fluke		
Fasciola hepatica	+	
Warbles (parasitic stages)		
Hypoderma bovis		+
H. lineatum		+
Mange mites		
Psoroptes bovis	+	+
Sarcoptes scabiei var bovis	+	+
Sucking lice		
Linognathus vituli	+	+
Haematopinus eurysternus	+	+
Solenopotes capillatus	+	+

PROLONGED ACTIVITY
When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, the product given at the recommended dosage of 1 ml per 50 kg bodyweight controls re-infection with the following nematodes up to the duration shown:

PARASITE	**NO. OF DAYS AFTER TREATMENT**
Barber's pole worm – *Haemonchus placei*	14
Small intestinal worm – *Cooperia spp*	14
Hairworm – *Trichostrongylus axei*	14
Brown stomach worm – *Ostertagia ostertagi*	21
Nodular worm – *Oesophagostomum radiatum*	21
Lungworm – *Dictyocaulus viviparous*	28

The veterinary medicinal product may also be used as an aid in the control of biting lice (*Damalinia bovis*) and the mange mite (*Chorioptes bovis*), but complete elimination may not occur.

5. Contraindications

This veterinary medicinal product is not to be used intramuscularly or intravenously.
This veterinary medicinal product is a low volume product authorised for use in cattle. It must not be used in other species as severe adverse reactions, including fatalities in dogs, may occur, especially Collies, Old English Sheepdogs and related breeds or crosses.
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 body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest

resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.
Resistance to ivermectin has been reported in *Ostertagia ostertagi* and *Cooperia* species in cattle within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of these helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:
This veterinary medicinal product does not contain any antimicrobial preservative. Swab septum before removing each dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke or eat whilst handling the veterinary medicinal product.
Wash hands after use.
Personal protective equipment consisting of gloves and glasses should be worn when handling the veterinary medicinal product. Direct contact with the skin should be avoided. Take care to avoid self-injection: the product may cause local irritation and/or pain at the injection site. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician.

Special precautions for the protection of the environment:
The veterinary medicinal 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.

Pregnancy and lactation:
Can be used in pregnancy and lactation.
Refer to withdrawal periods.

Fertility:
Can be used in breeding animals.

Overdose:
A dose of 25 ml product per 50 kg bodyweight (25 times the recommended dose level) may result in an injection site lesion, including tissue necrosis, oedema, fibrosis and inflammation. No other drug-related reactions have been observed.

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

7. Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Discomfort[1,2] Injection site swelling[2]

[1]Transitory.
[2]Resolves over time 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.

200 mcg of ivermectin and 2 mg of clorsulon per kg bodyweight corresponding to a single dose of 1 ml per 50 kg bodyweight.

	Bodyweight (kg)	50	100	150	200	250	300	350	400	450	500	550	600	650	700	750	800
	Dose (ml)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
50 ml	Number of cattle treatments/vial	50	25	16	12	10	8	7	6	5	5	4	4	3	3	3	3
250 ml	Number of cattle treatments/vial	250	125	83	62	50	41	35	31	27	25	22	20	19	17	16	15
500 ml	Number of cattle treatments/vial	500	250	166	125	100	83	71	62	55	50	45	41	38	35	33	31

9. Advice on correct administration

The veterinary medicinal product should be administered only by subcutaneous injection under the loose skin in front of or behind the shoulder.
Divide doses in excess of 10 ml between different injection sites and use different sites to those used for other parenteral medications.
A sterile 17 gauge ½ inch (15-20 mm) needle is recommended. Replace with a fresh sterile needle after every 10-12 animals or sooner if the needle becomes soiled.
When using the 500 ml pack size use only automatic syringe equipment. For the 50 ml pack size, use of a multidose syringe is recommended.
The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person.
To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively rather than individually, to avoid under- or over-dosing, they should be grouped according to their bodyweight and dosed accordingly.
When the temperature of the product is below 5°C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15°C will greatly increase the ease with which the product can be injected.

10. Withdrawal periods

Meat and offal: 66 days
Milk: Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the container in the outer carton in order to protect from light.

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

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 is extremely dangerous for fish and other aquatic organisms.

Do not contaminate surface waters or ditches with the product or used container.

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

Container material: High density polyethylene.
Container closure: Siliconised grey bromobutyl rubber stopper.
Container volume: 50, 250 or 500 ml.

Cardboard box with 1 x 50 ml bottle.
Cardboard box with 1 x 250 ml bottle.
Cardboard box with 1 x 500 ml bottle.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Tallaght, Dublin 24
Ireland

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information

MODE OF ACTION

Ivermectin acts on the nervous system of nematode and arthropod parasites. It first paralyses, then kills them. Clorsulon acts on enzymes involved in energy generation in liver fluke. At therapeutic usage rates the veterinary medicinal product has no effect on the equivalent systems of cattle.
At the recommended usage rate, the veterinary medicinal product has no adverse effects on breeding performance of cattle. At therapeutic usage rates it has no effect on the nervous system of cattle.

Pharmacotherapeutic group: Endectocides, macrocyclic lactones, avermectins**,** ivermectin – combinations.