A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PRINTED CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Plus, 10/100 mg/ml Solution for Injection for Cattle – UK

Ivermectin
Clorsulon

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 10 mg of ivermectin and 100 mg of clorsulon

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

50ml, 250ml or 500ml

5. TARGET SPECIES

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Read the package leaflet before use.

50ml Carton

Body weight(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
Number of	50	25	16	12	10	8	7	6	5	5	4	4	3	3	3	3

Cattle treatments / vial																

250ml Carton

Body weight (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
Number of Cattle treatments/ vial	250	125	83	62	50	41	35	31	27	25	22	20	19	17	16	15

500ml Carton

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
Number of Cattle treatments / vial	500	250	166	125	100	83	71	62	55	50	45	41	38	35	33	31

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.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:
Once broached use by 28 days.
Use by:

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4003

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE

PACK LABEL – for 50ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Plus, 10/100 mg/ml Solution for Injection for Cattle – UK

Ivermectin
Clorsulon

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY VOLUME

50ml

4. ROUTE(S) OF ADMINISTRATION

1ml per 50 kg bodyweight. SC

5. WITHDRAWAL PERIOD

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.

6. BATCH NUMBER

Batch no:

7. EXPIRY DATE

EXP:
Once broached use by 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

License number: Vm 50146/4003

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PACK LABEL for 250ml and 500ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Plus, 10/100 mg/ml Solution for Injection for Cattle

Ivermectin
Clorsulon

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 10 mg of ivermectin and 100 mg of clorsulon

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

250ml or 500ml

5. TARGET SPECIES

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1ml per 50 kg bodyweight, SC.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once broached use by 28 days.

11. SPECIAL STORAGE CONDITIONS

Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4003

17. MANUFACTURER'S BATCH NUMBER

Batch No:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Bimectin Plus, 10/100 mg/ml Solution for Injection for Cattle (Bimectin Fluke, 10/100 mg/ml, Solution for Injection for Cattle; Cevamec D, 10/100 mg/ml, Solution injectable pour bovins; Renomec Plus, 10/100 mg/ml, Solucion inyectable para bovinos; Maximec Plus, 10/100 mg/ml, Solution for injection for Cattle)Ivermectin/Clorsulon

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Plus, 10/100 mg/ml, Solution for Injection for Cattle
Ivermectin
Clorsulon

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml contains 10 mg of ivermectin and 100 mg of clorsulon

4. INDICATION(S)

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 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 heptica	+	
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 1ml per 50kg 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 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 product is not to be used intramuscularly or intravenously.

This 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. ADVERSE REACTIONS

Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These reactions disappeared without treatment.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

200µg of ivermectin and 2mg of clorsulon per kg bodyweight corresponding to a single dose of 1ml per 50kg 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 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 (15-20mm) needle is recommended. Replace with a fresh sterile needle after every 10-12 animals or sooner if the needle becomes soiled.
When using the 500ml pack size use only automatic syringe equipment. For the 50ml 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.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

12. SPECIAL WARNING(S)

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 use in animals
This product does not contain any antimicrobial preservative. Swab septum before removing each dose.
User Warnings
Do not smoke or eat whilst handling the product.
Wash hands after use.
Wear gloves and glasses 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.
Other precautions
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.
Use during pregnancy/ lactation.
Can be used in pregnancy and lactation.
Can be used in breeding animals.
Refer to withdrawal periods.
Overdose
A dose of 25ml product per 50kg 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.
Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

15. 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 product has no effect on the equivalent systems of cattle.
At the recommended usage rate the product has no adverse effects on breeding performance of cattle. At therapeutic usage rates it has no effect on the nervous system of cattle.

Commercial presentations:
box of 1 vial of 50ml
box of 1 vial of 250ml
box of 1 vial of 500ml

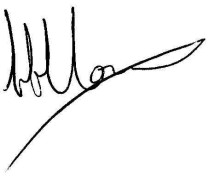
Not all pack sizes may be marketed.

Legal Category:.

For animal treatment only.

Marketing Authorisation Number: Vm 50146/4003

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



Approved 30 July 2019