PARTICULARS TO APPEAR ON THE OUTER PACKAGE (200 ml and 500 ml carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Classic Injection for Cattle and Sheep
(ivermectin)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sterile non-aqueous solution for injection containing 1% w/v ivermectin

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

200 ml
500 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATIONS

For the treatment and control of internal and external parasites of cattle and sheep.

CATTLE
IVOMEC CLASSIC Injection for Cattle and Sheep treats and controls gastro-intestinal nematodes, lungworms, warbles, mange mites and sucking lice and aids in the control of biting lice (Damalinia bovis) and the mange mite Chorioptes bovis,but complete elimination may not occur.

SHEEP
IVOMEC CLASSIC Injection for Cattle and Sheep treats and controls gastro-intestinal nematodes, lungworms, nasal bots and scab mites (*Psoroptes ovis*).

7. METHOD AND ROUTE OF ADMINISTRATION

CATTLE: IVOMEC CLASSIC Injection for Cattle and Sheep should be given to cattle only by subcutaneous injection in front or behind the shoulder, at the recommended

dosage rate of 1 ml per 50 kg bodyweight. A sterile 17 gauge 1/2 inch needle is recommended.

SHEEP: IVOMEC CLASSIC Injection for Cattle and Sheep should be given to sheep only by subcutaneous injection in the neck, at the recommended dosage rate of 0.5 ml per 25 kg bodyweight. A sterile 17 gauge 1/2 inch needle is recommended.

CATTLE: 1ml/50kg		**SHEEP: 0.5ml/25kg**	
Bodyweight (kg)	**Dose Volume (ml)**	**Bodyweight (kg)**	**Dose Volume (ml)**
up to 50	1.0	Up to 5	0.1
51-100	2.0	5.1-10	0.2
101-150	3.0	10.1-15	0.3
151-200	4.0	15.1-25	0.5
201-250	5.0	25.1-50	1.0
251-300	6.0	50.1-75	1.5
301-350	7.0	75.1-100	2.0
351-400	8.0		

For cattle weighing over 400 kg, calculate the dose at the rate of 1 ml per 50 kg bodyweight.
For sheep weighing over 100 kg, calculate the dose at the rate of 0.5 ml per 25 kg bodyweight.
Syringes must be filled from the vial through a dry, sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than 20 times. When treating sheep of less than 16 kg, seek veterinary advice regarding the use of 1ml disposable syringes graduated in increments of 0.1ml. When treating individual sheep, a syringe, not exceeding 2.0 ml and calibrated in increments of 0.1ml, should be used. When treating groups of animals, use only an automatic dosing device.
IVOMEC CLASSIC Injection for Cattle and Sheep can be administered to cows and ewes at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. It can be used in breeding ewes, rams, bulls and cows without affecting fertility.
IVOMEC CLASSIC Injection for Cattle and Sheep can be given to all ages of animals including young calves and lambs. Ivermectin is a member of the macrocyclic lactone class of endectocides.
Swab septum before removing each dose.
Use a dry sterile needle and syringe.
Use only automatic syringe equipment.

8. WITHDRAWAL PERIOD

Cattle (meat and offal) - 49 days.
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.

Sheep (meat and offal) - 37 days. As no milk withholding period has been established, do not treat lactating ewes where milk is to be used for human consumption.

9. SPECIAL WARNINGS

IMPORTANT: READ PACKAGE LEAFLET BEFORE USE
This product is specifically for use in these target species. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur. Do not inject intravenously or intramuscularly.

User Warnings:
Take care to avoid self injection: the product may cause local irritation and /or pain at the site of injection.
Do not smoke, drink or eat while handling the product.
Wash hands after use.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

This product does not contain any antimicrobial preservative
Protect from direct sunlight and store below 30°C.
Following withdrawal of the first dose, use the product within six months.
Discard unused material.

12. SPECIFIC 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 product or used container.
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of 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.

POM-VPS

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4188

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. FURTHER INFORMATION

For full details see package leaflet.
IF BROKEN, DO NOT ACCEPT

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (200 ml and 500 ml bottle label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Classic Injection for Cattle and Sheep
(ivermectin)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sterile non-aqueous solution for injection containing 1% w/v ivermectin

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

200 ml
500 ml

5. TARGET SPECIES

Cattle and Sheep

6. INDICATION(S)

For the treatment and control of internal and external parasites of cattle and sheep.

7. METHOD AND ROUTE OF ADMINISTRATION

TREATMENT: Inject subcutaneously at the rate of:
Cattle: 1 ml per 50 kg - Sheep: 0.5 ml per 25 kg

Swab septum before removing each dose.
Use a dry sterile needle and syringe.
Use only automatic syringe equipment.

8. WITHDRAWAL PERIOD

Cattle (meat and offal) - 49 days. Sheep (meat and offal) - 37 days. 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. Since no milk withholding period has been established, do not treat lactating ewes where milk is to be used for human consumption.

9. SPECIAL WARNINGS

IMPORTANT: READ PACKAGE LEAFLET BEFORE USE
Do not inject intravenously or intramuscularly. Take care to avoid self-injection: the product may cause local irritation and/or pain at the site of self-injection. Vial stoppers must not be broached more than 20 times. See package leaflet for details of appropriate syringes for use with IVOMEC CLASSIC Injection for Cattle and Sheep.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

This product does not contain any antimicrobial preservative.
Protect from direct sunlight and store below 30°C.
Following withdrawal of the first dose, use the product within six months.
Discard unused material.

12. SPECIFIC 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 product or used containerAny unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of 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.

POM-VPS

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4188

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. FURTHER INFORMATION

IVOMEC CLASSIC Injection for Cattle and Sheep belongs to the macrocyclic lactone class of endectocides.

PACKAGE LEAFLET FOR: Ivomec Classic Injection for Cattle and Sheep

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

Marketing Authorisation Holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Batch Release Site:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet
31000 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Classic Injection for Cattle and Sheep
(Ivermectin)

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

Sterile non-aqueous solution for injection containing 1% w/v ivermectin

4. INDICATIONS

For the treatment and control of internal and external parasites of cattle and sheep. IVOMEC CLASSIC Injection for Cattle and Sheep is indicated for the effective treatment and control of the following parasites of cattle and sheep:

CATTLE PARASITE	Adult	L_4	Inhibited L_4
Gastro-intestinal Roundworms:			
Ostertagia lyrata	•	•	
Ostertagia ostertagi	•	•	•
Cooperia oncophora	•	•	
Cooperia pectinata	•	•	
Cooperia punctata	•	•	
Haemonchus placei	•	•	

Trichostrongylus axei	•	•	
Trichostrongylus colubriformis	•	•	
Bunostomum phlebotomum	•	•	
Oesophagostomum radiatum	•	•	
Strongyloides papillosus	•		
Nematodirus helvetianus	•		
Nematodirus spathiger	•		
Trichuris spp.	•		
Lungworms:			
Dictyocaulus viviparus	•	•	
Eye Worms:			
Thelazia spp.	•		
Warbles:			
Hypoderma bovis			
H. lineatum			
Mange mites:			
Psoroptes bovis			
Sarcoptes scabiei var. *bovis*			
Sucking lice:			
Linognathus vituli			
Haematopinus eurysternus			
Solenopotes capillatus			

IVOMEC CLASSIC Injection for Cattle and Sheep 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 in Cattle

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with IVOMEC CLASSIC Injection at the recommended dose rate of 0.2 mg per kg bodyweight controls re-infection with:

	Prolonged Activity
Dictyocaulus viviparus	up to 28 days
Ostertagia ostertagi	up to 21 days
Oesophagostomum radiatum	up to 21 days
Cooperia spp.	up to 14 days
Trichostrongylus axei	up to 14 days
Haemonchus placei	up to 14 days

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.

SHEEP PARASITE	Adult	L_4	Inhibited L_4
Gastro-intestinal Roundworms:			
Ostertagia circumcincta	•	•	•
O. trifurcata	•	•	
Haemonchus contortus	•	•	•
Trichostrongylus axei	•		
T. colubriformis	•	•	
T. vitrinus	•		
Cooperia curticei	•	•	
Oesophagostomum columbianum	•	•	
O. venulosum	•		
Nematodirus filicollis	•	•	
Chabertia ovina	•	•	
Trichuris ovis	•		
Lungworms:			

Dictyocaulus filaria	•	•	
Protostrongylus rufescens	•		
Nasal Bots:			
Oestrus ovis			
Mange mites:			
Psoroptes ovis			

Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.

5. CONTRAINDICATIONS

IVOMEC CLASSIC Injection for Cattle and Sheep has been formulated specifically for use in these target species.

6. ADVERSE REACTIONS

Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.
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.

Immediately following subcutaneous injection, activity suggesting pain, sometimes intense but usually transient, has been observed in some sheep. These reactions disappeared without treatment.

7. TARGET SPECIES

Cattle and sheep

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

IVOMEC CLASSIC Injection for Cattle and Sheep should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg under the loose skin in front of, or behind, the shoulder in cattle and in the neck in sheep. Do not inject intravenously or intramuscularly.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle and

sheep. The injection may be given with any standard automatic, multiple-dose or single-dose hypodermic syringe. When using the 200 ml and 500 ml pack size use only automatic syringe equipment. Use of a 17 gauge 1/2 inch needle is suggested. Injection of wet or dirty animals is not recommended. If using a multiple-dose or single-dose hypodermic syringe, use a separate sterile needle to withdraw from the pack.

For example:
Cattle: 1 ml/50 kg bodyweight

Bodyweight (kg)	**Dose Volume (ml)**
up to 50	1
51-100	2
101-150	3
151-200	4
201-250	5
251-300	6
301-350	7
351-400	8
401-450	9
451-500	10
501-550	11
551-600	12

Sheep: 0.5 ml per 25 kg bodyweight. For young lambs weighing less than 12 kg give 0.1 ml per 5 kg and the use of a syringe that can deliver as little as 0.1 ml is recommended.
Use the following dosage schedule:

Bodyweight (kg)	**Dose Volume (ml)**
Up to 25	0.5
26-50	1
51-75	1.5
76-100	2.0

For the treatment and control of sheep scab, two injections with a seven-day interval are required to treat clinical signs of scab and to eliminate all living mites.

9. ADVICE ON CORRECT ADMINISTRATION TREATMENT PROGRAMMES

Seek advice of your veterinary surgeon.

Swab septum before removing each dose.
Use a dry, sterile needle and syringe.
When using the 200 ml and 500 ml pack sizes, use only automatic syringe equipment.

10. WITHDRAWAL PERIODS

Cattle (meat and offal) - 49 days.
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.

Sheep (meat and offal) - 37 days. As no milk withholding period has been established, do not treat lactating ewes where milk is to be used for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Protect from direct sunlight and store below 30°C.
Following withdrawal of the first dose, use the product within 6 months.
Discard unused material.

12. SPECIAL WARNINGS

This product does not contain any antimicrobial preservative.
Injection of wet or dirty animals is not recommended. If using a single-dose or hypodermic syringe, use a separate sterile needle to withdraw from the pack.
Treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although a clinical improvement may be seen, elimination of all mites may not occur. Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasite of sheep. Following treatment of infected sheep, great care must be taken to avoid re-infestation, as mites may be viable for up to 15 days off the sheep. It is important to ensure all sheep which have been in contact with infected sheep are treated. Contact between treated infected and non-treated, non-infected flocks must be avoided until at least 7 days after the last treatment.

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 macrocyclic lactones (which includes ivermectin) has been reported in *Teladorsagia* spp. in sheep and in *Cooperia* spp. in cattle within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

USER WARNINGS

Do not smoke, drink or eat while handling the product.
Wash hands after use.
Take care to avoid self injection: the product may cause local irritation and /or pain at the site of injection. In case of accidental self-injection, seek medical advice and show the label or package leaflet to the physician.

For animal treatment only.
Keep out of reach of children.

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

Do not contaminate surface waters or ditches with product or used container.
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM-VPS

Vm 08327/4188

To be supplied only on veterinary prescription.
Further information is available on request.
Ivermectin is a member of the macrocyclic lactone class of endectocides.

INTRODUCTION

IVOMEC CLASSIC Injection for Cattle and Sheep is an injectable parasiticide. One low-volume dose effectively controls internal and external parasites that impair livestock health and productivity.

PRODUCT DESCRIPTION

IVOMEC CLASSIC Injection for Cattle and Sheep is a ready-to-use, sterile, non-aqueous 1.0% w/v solution of ivermectin. Ivermectin is a derivative from the avermectin family of highly active, broad-spectrum antiparasitic agents which are isolated from fermentation of *Streptomyces avermitilis*.

PACKAGE INFORMATION

IVOMEC CLASSIC Injection for Cattle and Sheep is available in two ready-to-use sizes: 200 ml and 500 ml. The 200 ml and 500 ml packs are soft, collapsible packs designed for use with automatic injection equipment. The injection may be given with any standard automatic or single-dose or hypodermic syringe. Full list of pack sizes: 50ml, 200ml, 500ml 1L. Not all pack sizes may be marketed.

Approved 06 October 2020