

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {1L, 2.5L and 2x2.5L
CARTONS}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Classic pour-on for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear pour-on solution containing 0.5% w/v ivermectin

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

1L

2.5L

2 x 2.5L

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment and control of gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle.

This pack treats 33 x 300 kg cattle.

This pack treats 83 x 300 kg cattle.

Ivomec Classic Pour-On at the recommended dosage level of 500 mcg ivermectin per kg bodyweight effectively controls the following parasites of cattle.

PARASITE	Adult	L4	Inhibited L4
Gastro-intestinal Roundworms:			
<i>Ostertagia ostertagi</i>	•	•	•
<i>Cooperia</i> spp.	•	•	
<i>Haemonchus placei</i>	•	•	
<i>Trichostrongylus axei</i>	•	•	
<i>Trichostrongylus colubriformis</i>	•	•	
<i>Oesophagostomum radiatum</i>	•	•	
<i>Strongyloides papillosus</i>	•		
<i>Trichuris</i> spp.	•		
Lungworms:			
<i>Dictyocaulus viviparus</i>	•	•	
Eye Worms:			
<i>Thelazia</i> spp.	•		
	Adult	Immature	
Warbles (parasitic stages):			
<i>Hypoderma bovis</i>		•	
<i>H. lineatum</i>		•	
Mange Mites:			
<i>Chorioptes bovis</i>	•	•	
<i>Sarcoptes scabiei</i> var. <i>bovis</i>	•	•	
Lice:			
<i>Linognathus vituli</i>	•	•	
<i>Solenopotes capillatus</i>	•	•	
<i>Haematopinus eurysternus</i>	•	•	
<i>Damalinia bovis</i>	•	•	

Prolonged Activity

Ivomec Classic Pour-On for Cattle given at the recommended dosage of 500 mcg ivermectin per kg bodyweight controls infections with the following parasites:

	Prolonged Activity
<i>Haematobia irritans</i>	up to 35 days
<i>Dictyocaulus viviparus</i>	up to 28 days
<i>Ostertagia ostertagi</i>	up to 21 days
<i>Oesophagostomum radiatum</i>	up to 21 days
<i>Cooperia spp.</i>	up to 14 days
<i>Trichostrongylus axei</i>	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.

Rainfall before or after treatment does not affect the efficacy of Ivomec Classic Pour-On for Cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg ivermectin/kg bodyweight).

Administration: The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

Bodyweight kg	Dose Volume (mL)	Doses per 1 Litre Pack	Doses per 2.5 Litre Pack
100	10	100	250
150	15	66	166
200	20	50	125
250	25	40	100
300	30	33	83

Over 300 kg bodyweight, give 1 ml per 10 kg bodyweight.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

8. WITHDRAWAL PERIOD

Meat and offal: 15 days

Do not use in cows 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

User Warnings:

HIGHLY FLAMMABLE-KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.

May be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear nitrile rubber gloves and boots with a waterproof coat when applying the product. Wash all protective clothing after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If irritation persists, seek medical advice and show the package leaflet or label to the doctor. If accidental eye exposure occurs, flush the eyes immediately with plenty of water and get medical attention.

Do not smoke or eat while handling the product.

Wash hands after use.

Use only in well-ventilated areas or outdoors.

For external use only.

No smoking

Keep away from sources of ignition

Keep container tightly closed

Ivomec Classic Pour-On for Cattle has been formulated for topical application specifically in cattle. Do not apply or administer to any other species as severe adverse reactions, including fatalities in dogs, may occur.

RESISTANCE MANAGEMENT

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.

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 *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.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Avoid extremes of temperature and protect from light. Close container when not in use. Store in tightly closed original container. Store upright. The dosing cup should not be stored attached to the bottle when not in use. Remove the cup after each use and replace with the bottle cap.

If stored at temperatures below 0°C, Ivomec Classic Pour-On for Cattle may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy. Keep the container in the outer carton.

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

CONTAINER DISPOSAL - 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.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

For animal treatment only.

POM-VPS

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

Keep out of the reach and sight 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 08327/4169

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {1 litre and 2.5 litre bottle front and back labels}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Classic Pour-On for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear pour-on solution containing 0.5% w/v ivermectin

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

1 Litre

2.5 Litres

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment and control of gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle treatment

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg ivermectin per kg bodyweight).

Administration: The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

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

IMPORTANT: Read Package Leaflet Before Use

8. WITHDRAWAL PERIOD

Meat and offal: 15 days

Do not use in cows 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

User Warnings

HIGHLY FLAMMABLE-KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION

May be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear nitrile rubber gloves and boots with a waterproof coat when applying the product. Wash all protective clothing after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If irritation persists, seek medical advice and show the package leaflet or label to the doctor. If accidental eye exposure occurs, flush the eyes immediately with plenty of water and get medical attention.

Do not smoke or eat while handling the product.

Wash hands after use.

Use only in well-ventilated areas or outdoors.

For external use only.

No smoking

Keep away from sources of ignition

Keep container tightly closed

Ivomec Classic Pour-On for Cattle has been formulated for topical application specifically in cattle. Do not apply or administer to any other species as severe adverse reactions, including fatalities in dogs, may occur.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Avoid extremes of temperature and protect from light. Close container when not in use. Store in tightly closed original container. Store upright.

If stored at temperatures below 0°C, Ivomec Classic Pour-On for Cattle may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

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

CONTAINER DISPOSAL - 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.

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 and sight 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 08327/4169

17. MANUFACTURER’S BATCH NUMBER

Batch No:

PACKAGE LEAFLET FOR: Ivomec Classic Pour-on for Cattle

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

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 Pour-on for cattle.

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

A clear pour-on solution containing 5 mg/ml ivermectin.

4. INDICATION(S)

For the treatment and control of gastro-intestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle.

MODE OF ACTION

Ivermectin paralyses and ultimately kills parasitic nematodes, arachnids, and insects by its effect on the nervous systems of these parasites. At therapeutic doses, ivermectin does not readily penetrate the central nervous systems of cattle. Ivermectin belongs to the avermectin class of anthelmintic endectocides. The mode of action exhibited by the avermectins is unique to this class of antiparasitic agents.

Ivomec Classic Pour-On at the recommended dosage level of 500 mcg ivermectin per kg bodyweight effectively controls the following parasites of cattle:

PARASITE	Adult	L4	Inhibited L4
Gastro-intestinal Roundworms:			
<i>Ostertagia ostertagi</i>	•	•	•
<i>Cooperia</i> spp.	•	•	
<i>Haemonchus placei</i>	•	•	
<i>Trichostrongylus axei</i>	•	•	
<i>Trichostrongylus colubriformis</i>	•	•	
<i>Oesophagostomum radiatum</i>	•	•	
<i>Strongyloides papillosus</i>	•		
<i>Trichuris</i> spp.	•		
Lungworms:			
<i>Dictyocaulus viviparus</i>	•	•	
Eye Worms:			
<i>Thelazia</i> spp.	•		
	Adult	Immature	
Warbles (parasitic stages):			
<i>Hypoderma bovis</i>		•	
<i>H. lineatum</i>		•	
Mange Mites:			
<i>Chorioptes bovis</i>	•	•	
<i>Sarcoptes scabiei</i> var. <i>bovis</i>	•	•	
Lice:			
<i>Linognathus vituli</i>	•	•	
<i>Solenopotes capillatus</i>	•	•	
<i>Haematopinus eurysternus</i>	•	•	
<i>Damalinia bovis</i>	•	•	

Prolonged Activity

Ivomec Classic Pour-On for Cattle given at the recommended dosage of 500 mcg ivermectin per kg bodyweight controls infections with the following parasites:

	Prolonged Activity
<i>Haematobia irritans</i>	up to 35 days
<i>Dictyocaulus viviparus</i>	up to 28 days
<i>Ostertagia ostertagi</i>	up to 21 days
<i>Oesophagostomum radiatum</i>	up to 21 days
<i>Cooperia spp.</i>	up to 14 days
<i>Trichostrongylus axei</i>	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.

Rainfall before or after treatment does not affect the efficacy of Ivomec Classic Pour-On for Cattle.

5. CONTRAINDICATIONS

CONTRA-INDICATIONS, WARNINGS, ETC.

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

6. ADVERSE REACTIONS

SAFETY

Studies have demonstrated a wide safety margin and use at the level recommended had no adverse effect on breeding performance.

7. TARGET SPECIES

Cattle

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

DOSAGE AND ADMINISTRATION

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg ivermectin per kg bodyweight).

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Administration: The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

This product is formulated only for external application to cattle; do not use in other species.

9. ADVICE ON CORRECT ADMINISTRATION

PACKAGING

IVOMEK CLASSIC Pour-On for Cattle is available in either 250 ml and 1 litre packs with a measure-squeeze-pour system or a 2.5 litre collapsible backpack.

Dosing cup with Measure-Squeeze-Pour System (250 ml and 1 litre bottles)

The 250 ml pack contains one 25 ml dosing cup and one dip tube.

The 1 litre pack contains one 60 ml dosing cup and one dip tube.

- Insert the dip tube into base of the dosing cup. Leave the “slotted end” of the dip tube exposed in the bottom of the bottle.
- Unscrew the bottle cap from the top of the bottle. Screw the dosing cup onto the top of the bottle.
- Measure: To select the correct dose rate, rotate the adjuster cap at the top of the cup in either direction to position the dose indicator to the weight of the animal you want to treat. When body weight is between markings, use the higher setting.
- Squeeze the bottle gently to fill the dosing cup to the required dose. Release your grip and any excess will return to the bottle.
- Pour: Apply the full dose by tipping and pouring along the backline of the animal until the dosing cup is empty.
- The dosing cup should not remain attached to the bottle when not in use. Detach the dosing cup after each use and replace the bottle cap.

Important - Keep upright when filling and during storage.

Collapsible backpack (2.5 litre pack)

- Connect the pour-on applicator to the collapsible pack as follows:
- Attach the open end of the draw-off tubing to the pour-on applicator.**
- Attach draw-off tubing to the cap with the stem. Replace the shipping cap with the cap that has the draw-off tubing. Tighten the draw-off cap.
- Gently prime the pour-on applicator, checking for leaks.
- Follow manufacturer's directions for correct use and care of the equipment.

** An applicator compatible with this formulation is available for use with IVOMEK CLASSIC Pour-On for Cattle. Other applicators may be incompatible with the formulation and could result in locking, incorrect dosage or leakage.

10. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 15 days

Do not use in cows 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

The dosing cup should not be stored attached to the bottle when not in use. Remove the cup after each use and replace with the bottle cap. Store in tightly closed original container. Store upright.

If stored at temperatures below 0°C, IVOMEK CLASSIC Pour-On for Cattle may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

12. SPECIAL WARNING(S)

User warnings

HIGHLY FLAMMABLE-KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION

May be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear nitrile rubber gloves and boots with a waterproof coat when applying the product. Wash all protective clothing after use.

If accidental skin contact occurs, wash the affected area immediately with soap and water. If irritation persists, seek medical advice and show the package leaflet or label to the doctor. If accidental eye exposure occurs, flush the eyes immediately with plenty of water and get medical attention.

Do not smoke or eat while handling the product.

Wash hands after use.

Use only in well-ventilated areas or outdoors.

For external use only.

For animal treatment only.

Keep out of the reach and sight of children.

No smoking

Keep away from sources of ignition

Keep container tightly closed

USE DURING PREGNANCY OR LACTATION

The product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. It will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

RESISTANCE MANAGEMENT

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.

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 *Cooperia spp.* and *Ostertagia ostertagi* in cattle within the EU. Therefore, the use of this and other similar macrocyclic lactone products 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.

Ivomec Classic Pour-On for Cattle has been formulated for topical application specifically in cattle. It should not be applied or administered to other species, as severe adverse reactions, including fatalities in dogs, may occur. Avoid extremes of temperature and protect from light.

For Animal Treatment Only

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

ENVIRONMENTAL SAFETY

CONTAINER DISPOSAL - 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

15. OTHER INFORMATION

POM-VPS

To be supplied only on veterinary prescription.

Vm 08327/4169

Approved 06 October 2020

