PARTICULARS TO APPEAR ON THE OUTER PACKAGE (50 ml carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panomec Injection for cattle, sheep and pigs

(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

50 ml

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION

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

For full details see package leaflet.

7. METHOD AND ROUTE OF ADMINISTRATION

DOSAGE AND ADMINISTRATION
Cattle:
PANOMEC Injection for cattle, sheep and pigs should be given to cattle only by subcutaneous injection in front of or behind the shoulder, at the recommended dose rate of 1 ml per 50 kg bodyweight. A sterile 17 gauge 1/2 inch needle is recommended.

Sheep:
PANOMEC Injection for cattle, sheep and pigs should be given to sheep only by subcutaneous injection in the neck, at the recommended dose rate of 0.5 ml per 25 kg bodyweight. A sterile 17 gauge 1/2 inch needle is recommended. Although one injection controls internal parasites and may result in clinical improvement of sheep scab, two injections with a 7 day interval are required to eliminate all living *Psoroptes ovis* mites.

Pigs:
PANOMEC Injection for cattle, sheep and pigs should be given to pigs only subcutaneously in the neck, at the recommended dosage level of 1 ml per 33 kg bodyweight. A sterile 17 gauge 1/2 inch needle is recommended.

Cattle (1 ml/50 kg)		Sheep (0.5 ml/25 kg)		Pigs (1 ml/33 kg)	
Bodyweight (kg)	Dose Volume (ml)	Bodyweight (kg)	Dose Volume (ml)	Bodyweight (kg)	Dose Volume (ml)
Up to 50	1.0	Up to 5	0.1	Less than 4	0.1
51 – 100	2.0	5.1 – 10	0.2	5 – 7	0.2
101 – 150	3.0	10.1 – 15	0.3	8 – 10	0.3
151 – 200	4.0	15.1 – 25	0.5	11 – 13	0.4
201 – 250	5.0	25.1 – 50	1.0	14 – 16	0.5
251 – 300	6.0	50.1 – 75	1.5	17 – 33	1.0
301 – 350	7.0	75.1 – 100	2.0	34 – 50	1.5
351 - 400	8.0			51 – 66	2.0
				67 – 99	3.0
				100 – 133	4.0
				134 – 166	5.0
				167 – 200	6.0
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		For pigs weighing over 200 kg calculate the dose at the rate of 1 ml per 33 kg bodyweight	

When treating pigs and sheep of less than 16 kg, seek veterinary advice regarding the use of 1 ml disposable syringes graduated in increments of 0.1 ml.
When treating individual sheep, a syringe, not exceeding 2 ml and calibrated in increments of 0.1 ml, should be used.
When treating groups of animals use only an automatic dosing device (with vented draw-off apparatus when using the 50 ml vial).

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.

8. WITHDRAWAL PERIODS

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

Pigs (meat) - 19 days.

9. SPECIAL WARNINGS, IF NECESSARY

IMPORTANT
Read package leaflet before use.

PRECAUTIONS
Do not use this product intramuscularly or intravenously.

PANOMEC Injection for cattle, sheep and pigs has been formulated specifically for use in these target species. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.
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.

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.

Pharmaceutical Precautions
• This product does not contain an antimicrobial preservative.
• Swab septum before removing each dose.
• Use a dry sterile needle and syringe.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

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. 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 ponds, waterways or ditches with the product or empty container.
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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 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 08327/4193

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. ADDITIONAL INFORMATION

Ivermectin belongs to the avermectin (3-AV) class of anthelmintic endectocides.

To be supplied only on veterinary prescription.

If broken, do not accept.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (50 ml label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panomec Injection for cattle, sheep and pigs

(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

50 ml

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION

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

IMPORTANT: Read package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Treatment
Inject subcutaneously at the following dose rate:
Cattle: ..... 1.0 ml per 50 kg
Sheep: ..... 0.5 ml per 25 kg
Pigs: ..... 1.0 ml per 33 kg

8. WITHDRAWAL PERIODS

Cattle (meat) - 49 days.
Sheep (meat) - 37 days.
Pigs (meat) - 19 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, IF NECESSARY

PRECAUTIONS:
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.
Two injections, 7 days apart are needed.
Do not use this product intramuscularly or intravenously.
Vial stoppers must not be broached more than 20 times. See package leaflet for details of appropriate syringes for use with PANOMEC Injection for cattle, sheep and pigs.
Do not smoke, drink or eat while handling the product. Wash hands after use.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

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

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 ponds, waterways or ditches with the product or empty container.
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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 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 08327/4193

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. ADDITIONAL INFORMATION

Ivermectin belongs to the avermectin (3-AV) class of anthelmintic endectocides.
To be supplied only on veterinary prescription.

PACKAGE LEAFLET FOR:

Panomec Injection for cattle, sheep and pigs (ivermectin)

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panomec Injection for cattle, sheep and pigs
(ivermectin)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

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

4. INDICATION

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

Product Indications
PANOMEC Injection for cattle, sheep and pigs is indicated for the effective treatment and control of the following parasites of cattle, sheep and pigs:

CATTLE

PARASITE	Adullt	L_4	Inhibited L_4
Gastrointestinal 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	

PANOMEC Injection for cattle, sheep and pigs 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
When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with PANOMEC Injection for cattle, sheep and pigs at the recommended dosage of 0.2 mg per kg bodyweight controls re-infection with

Parasite	**No. of Days After Treatment**
Barbers 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 viviparus*	28

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	**Adullt**	**L_4**	**Inhibited L_4**
Gastrointestinal 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**		

* For the treatment and control of sheep scab, two injections with a 7 day interval are required to treat clinical signs of scab and to eliminate living mites.

PIGS

PARASITE	Adullt	L_4
Gastrointestinal roundworms		
Ascaris suum	•	•
Hyostrongylus rubidus	•	•
Oesophagostomum spp.	•	•
*Strongyloides ransomi***	•	
Lungworms		
Metastrongylus spp.	•	
Lice		
Haematopinus suis		
Mange mites		
Sarcoptes scabiei var. *suis*		

**Includes somatic larval stages.

5. CONTRAINDICATIONS

Do not use this product intramuscularly or intravenously.
PANOMEC Injection for cattle, sheep and pigs has been formulated specifically for use in these target species. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

Transitory discomfort has been observed in some cattle following subcutaneous injection. 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.
Further information is available on request.

7. TARGET SPECIES

Cattle, sheep and pigs.

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

Dosage and Administration
Cattle: 1 ml per 50 kg bodyweight.

Sheep: 0.5 ml per 25 kg bodyweight.
For the treatment and control of sheep scab, two injections with a 7 day interval are required to treat clinical signs of scab and to eliminate mites.

Pigs: 1 ml per 33 kg of bodyweight.

For cattle and sheep, PANOMEC Injection for cattle, sheep and pigs should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle and in sheep.

For pigs PANOMEC Injection for cattle, sheep and pigs should be given only subcutaneously in the neck in pigs at the recommended dosage level of 300 mcg ivermectin per kg of bodyweight.

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle and sheep and 33 kg of bodyweight of pigs.

The injection may be given with any standard automatic, multiple-dose or single-dose hypodermic syringe. Use of a 17 gauge ½ inch needle is suggested. Injection of wet or dirty animals is not recommended.

When treating groups of animals use only an automatic dosing device (with vented draw-off apparatus when using the 50 ml vial). If using a multiple-dose or single-dose hypodermic syringe, use a separate dry sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than 20 times.

Use this chart as a guide in working out the appropriate dose rate:

Cattle (1 ml/50 kg)		Sheep (0.5 ml/25 kg)		Pigs (1 ml/33 kg)	
Bodyweight (kg)	Dose Volume (ml)	Bodyweight (kg)	Dose Volume (ml)	Bodyweight (kg)	Dose Volume (ml)
Up to 50	1.0	Up to 5	0.1	Less than 4	0.1
51 – 100	2.0	5.1 – 10	0.2	5 – 7	0.2
101 – 150	3.0	10.1 – 15	0.3	8 – 10	0.3
151 – 200	4.0	15.1 – 25	0.5	11 – 13	0.4
201 – 250	5.0	25.1 – 50	1.0	14 – 16	0.5
251 – 300	6.0	50.1 – 75	1.5	17 – 33	1.0
301 – 350	7.0	75.1 – 100	2.0	34 – 50	1.5
351 - 400	8.0			51 – 66	2.0
				67 – 99	3.0
				100 – 133	4.0
				134 – 166	5.0
				167 – 200	6.0
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		For pigs weighing over 200 kg calculate the dose at the rate of 1 ml per 33 kg bodyweight	

9. ADVICE ON CORRECT ADMINISTRATION

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

When treating pigs and sheep of less than 16 kg, seek veterinary advice regarding the use of 1 ml disposable syringes graduated in increments of 0.1 ml. When treating individual sheep, a syringe, not exceeding 2 ml and calibrated in increments of 0.1 ml, should be used.

Treatment Programmes:
Seek the advice of your veterinary surgeon.

10. WITHDRAWAL PERIODS

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

Pigs (meat) - 19 days.

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

Precautions

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.

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 *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.

Pharmaceutical Precautions
This product does not contain an antimicrobial preservative.
Swab septum before removing each dose.
Use a dry sterile needle and syringe.

For Animal Treatment Only.

Keep out of reach of children.

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

CONTAINER DISPOSAL:
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or empty container.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Introduction
PANOMEC Injection for cattle, sheep and pigs is an injectable parasiticide. One low-volume dose effectively controls internal and external parasites that can impair livestock health and productivity.

PANOMEC Injection for cattle, sheep and pigs contains ivermectin. Its convenience, broad-spectrum efficacy and wide safety margin make it an ideal product for controlling parasites of cattle, sheep and pigs.

Product Description
PANOMEC Injection for cattle, sheep and pigs is a ready-to-use, sterile, non-aqueous 1.0% w/v solution of ivermectin. Ivermectin is a member of the avermectin family of highly active, broad-spectrum antiparasitic agents which are isolated from fermentation of *Streptomyces avermitilis*.

PANOMEC Injection for cattle, sheep and pigs is formulated to deliver the recommended dose level of 200 mcg ivermectin per kg bodyweight in cattle and sheep and 300 mcg ivermectin per kg bodyweight in pigs.

Ivermectin belongs to the macrocyclic lactone (3-ML) class of endectocides.

POM-VPS

Vm 08327/4193

To be supplied only on veterinary prescription.

Approved 28 May 2020