

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Injection for Pigs
(Ivermectin)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

500 ml
200 ml

5. TARGET SPECIES

Pigs

6. INDICATIONS

For the treatment and control of internal and external parasites of pigs.

IVOMEC controls the following internal and external parasites which impact on the health of pigs.

PARASITE	Adult	L4
Gastrointestinal Roundworms		
<i>Ascaris suum</i>	•	•
<i>Hyostrogylus rubidus</i>	•	•
<i>Oesophagostomum spp</i>	•	•
<i>Strongyloides ransomi</i> *	•	
Lungworms		
<i>Metastrongylus spp</i>	•	
Lice		
<i>Haematopinus suis</i>		
Mange Mites		
<i>Sarcoptes scabiei var. suis</i>		

* Includes somatic larval stages.

7. METHOD AND ROUTES OF ADMINISTRATION

Dosage and Administration

- IVOMEK should be injected subcutaneously in the neck.
- Use at a rate of 1 ml/33 kg bodyweight.
- The use of a 17 gauge x 1/2-inch needle is recommended.

This table indicates the recommended dose volumes for various bodyweights and the number of doses/pack.

In pigs, especially those under 16 kg for which less than 0.5 ml of IVOMEK is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver 0.1 ml is recommended.

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. For piglets weighing less than 16 kg administer at a dose rate of 0.1 ml/3 kg bodyweight.

Bodyweight (kg)	Dose Volume (ml)	Doses Per Pack	
		200 ml	500 ml
8	0.25	800	2000
8-16	0.5	400	1000
17-33	1.0	200	500
34-50	1.5	133	330
51-66	2.0	100	250
67-99	3.0	66	166
100-133	4.0	50	125
134-166	5.0	40	100
167-200	6.0	32	83

Over 200 kg bodyweight, give 1.0 ml/33 kg bodyweight.

8. WITHDRAWAL PERIOD

Pigs must not be treated within 19 days of slaughter for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Precautions

This product is not for intravenous or intramuscular use.

IVOMEK Injection for Pigs is a low-volume product registered for use in pigs. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

Transient discomfort occurs occasionally in injected pigs.

Do not smoke, drink or eat while handling the product.
Wash hands after use.

Take care to avoid accidental self-injection; the product may cause local irritation and/or pain at the injection site.

Swab septum before removing each dose.
Use a dry sterile needle and syringe.
Do not use after the expiry date indicated.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Protect from direct sunlight.
Do not store above 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 surface waters or ditches with product or used 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 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 08327/4179

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. ADDITIONAL INFORMATION

IMPORTANT: Read package leaflet before use.

To be supplied only on veterinary prescription.

Further information is available on request.

If broken, do not accept.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec injection for pigs
(Ivermectin)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

500 ml
200 ml

5. TARGET SPECIES

Pigs

6. INDICATIONS

For the treatment and control of gastro-intestinal roundworms, lungworms, lice and mange mites of pigs.

7. METHOD AND ROUTES OF ADMINISTRATION

Inject subcutaneously in the neck at the rate of 1.0 ml per 33 kg bodyweight.

8. WITHDRAWAL PERIOD

Pigs must not be treated within 19 days of slaughter for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Precautions

This product is not for intravenous or intramuscular use.

IVOMEC Injection for Pigs is a low-volume product registered for use in pigs. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

Do not smoke, drink or eat while handling the product.
Wash hands after use.

Take care to avoid accidental self-injection; the product may cause local irritation and/or pain at the injection site.

Do not use after the expiry date indicated.

See package leaflet for details of appropriate syringes for use with IVOMEK Injection for Pigs.

Vial stoppers must not be breached more than 20 times.

Swab septum before removing each dose.

This product does not contain an antimicrobial preservative.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Protect from direct sunlight.

Do not store above 30°C.

Following withdrawal of the first dose, use the product within 6 months.

Discard unused material.

Once breached, use by

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 product or used 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 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 08327/4179

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. ADDITIONAL INFORMATION

IMPORTANT: Read package leaflet before use.

To be supplied only on veterinary prescription.

Further information is available on request.

PACKAGE LEAFLET FOR: Ivomec Injection for 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

Ivomec Injection for Pigs (ivermectin)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

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

4. INDICATIONS

For the treatment and control of internal and external parasites of pigs.

IVOMEC Injection is indicated for the effective treatment and control of the following harmful parasites of pigs:

PARASITE	Adult	L4
Gastrointestinal Roundworms		
<i>Ascaris suum</i>	•	•
<i>Hyostrongylus rubidus</i>	•	•
<i>Oesophagostomum spp</i>	•	•
<i>Strongyloides ransomi</i> *	•	
Lungworms		
<i>Metastrongylus spp</i>	•	
Lice		
<i>Haematopinus suis</i>		
Mange Mites		
<i>Sarcoptes scabiei var. suis</i>		

* Includes somatic larval stages.

5. CONTRAINDICATIONS

This product is not for intravenous or intramuscular use.

IVOMEC Injection for Pigs is a low-volume product registered for use in pigs. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

Transient discomfort occurs occasionally in injected pigs.

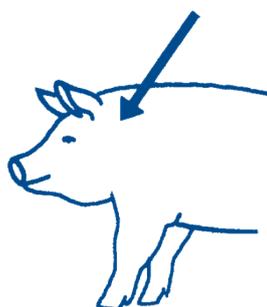
7. TARGET SPECIES

Pigs.

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

IVOMEK should be injected subcutaneously in the neck. Use at a rate of 1 ml/ 33 kg of bodyweight.

The use of a 17 gauge x 1/2- inch needle is recommended.



The injection may be given with any standard automatic multi-dose injection equipment or single dose syringe. As with any injection, aseptic technique should be used. Injecting animals with wet or dirty skins is not recommended. 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 breached more than 20 times.

For producers wishing to treat a small number of animals it is recommended that they use the 50 ml size of PANOMEK® Injection which is available from veterinary surgeons.

This table indicates the recommended dose volumes for various bodyweights and the number of doses per pack. In young pigs, especially those weighing under 16 kg for which less than 0.5 ml of IVOMEK is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver 0.1 ml is recommended. For piglets weighing less than 16 kg give at 0.1 ml/3 kg.

Bodyweight (kg)	Dose Volume (ml)	Doses Per Pack	
		200 ml	500 ml
8	0.25	800	2000
8-16	0.5	400	1000
17-33	1.0	200	500
34-50	1.5	133	330
51-66	2.0	100	250

67-99	3.0	66	166
100-133	4.0	50	125
134-166	5.0	40	100
167-200	6.0	32	83

Over 200 kg bodyweight, give 1.0 ml per 33 kg bodyweight.

When treating pigs 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 groups of animals use only an automatic dosing device.

9. ADVICE ON CORRECT ADMINISTRATION

RECOMMENDED TREATMENT PROGRAMME

BREEDING ANIMALS

At the time of initiating any parasite control programme, it is important to treat all breeding animals in the herd. After the initial treatment use IVOMEC regularly as follows:

Sows

Treat 7–14 days prior to farrowing

Gilts

Treat 7–14 days prior to service

Treat 7–14 days prior to farrowing

Boars

Boars are a key source of infestation of mange and other parasites.

Treat at least twice per year.

Arrivals and transfers

Treat on arrival and isolate for 7–10 days before mixing with the rest of the herd.

The above programme is a guide for effective parasite control using IVOMEC.

Alternatively, control can be achieved by “whole herd treatments” at six monthly intervals.

Fatteners

All pigs received for fattening should be treated before placement in clean quarters.

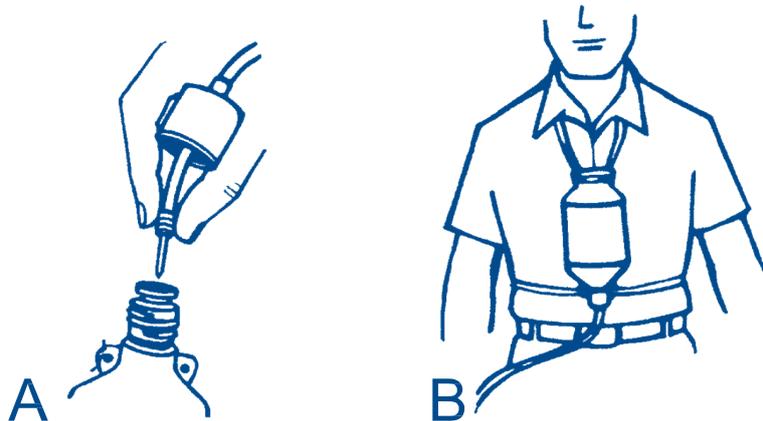
Note (1): For effective mange control, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities.

Note (2): Since louse eggs are unaffected by ivermectin and may take up to three weeks to hatch, retreatment may be necessary.

INSTRUCTIONS FOR USE WITH AUTOMATIC INJECTION EQUIPMENT

- Remove cap from the IVOMEC bottle and disinfect the rubber stopper (septum) with alcohol or another suitable chemical disinfectant.
- Hold the bottle upright and fully insert a draw-off needle into centre of rubber stopper (see illustration A). Secure firmly with the screw-on cap that is attached to tube.

- Hang the bottle comfortably in an inverted position from neck (see illustration B), shoulder or belt.
- Gently prime injector. The equipment is now ready for use.
- After use, remove the draw-off assembly from the pack and flush out entire apparatus with sterile water before storing.
- With single dose injectors disinfect the septum before each withdrawal.
- Store a partly-used bottle in the carton to protect it from light. Do not re-use empty bottles.
- Only use sterile needles, syringes and draw-off assemblies.



10. WITHDRAWAL PERIOD

Pigs must not be treated within 19 days of slaughter for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Store the bottle in its carton to protect it from light.

Do not store above 30°C.

Following withdrawal of the first dose, use the product within 6 months.

Discard unused material.

Do not use after the expiry date.

When the container is broached for the first time, using the in-use shelf-life which is specified on the package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNINGS

Do not smoke, drink or eat while handling the product.

Wash hands after use.

Take care to avoid accidental self-injection; the product may cause local irritation and/or pain at the injection site.

For Animal Treatment Only

Keep out of the reach of children.

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 product or used 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

POM-VPS

Vm 08327/4179

To be supplied only on veterinary prescription.

INTRODUCTION

IVOMEK Injection for Pigs is an injectable endectocide licensed for use in pigs. One low-volume dose effectively controls the important internal and external parasites which impact on the health of pigs.

PRODUCT DESCRIPTION

IVOMEK is a ready-to-use 1% w/v sterile non-aqueous solution of ivermectin.

Mode of action

The exposure of various parasitic nematodes and arthropods to ivermectin results in paralysis and thereafter death due to interference with the transmission of nerve impulses at synapses.

PRODUCT ADVANTAGES

Broad spectrum

IVOMEK Injection for Pigs provides an outstanding and proven standard of parasite control.

Safety

Studies and widespread use over many years have demonstrated the wide margin of safety of IVOMEK Injection. IVOMEK can be used at any stage in the breeding or production cycle.

Dosing accuracy

The low volume injection increases dosing accuracy.

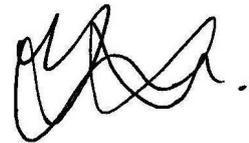
Ease of use

No special handling or protective clothing is necessary. IVOMEK Injection replaces the need for combination of sprays or pour-ons and in-feed wormers.

Convenient packaging

IVOMEK Injection for Pigs is available in 200 ml and 500 ml bottles. Both packs are soft collapsible presentations designed for use with automatic injection equipment.

For those producers wishing to treat individual or small numbers of animals it is suggested that they use the 50 ml presentation of PANOMEK® Injection. This is available from veterinary surgeons.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 28 May 2020