SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVOMEC Injection for Pigs
(ivermectin)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ivermectin 10 mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Indicated for the treatment and control of the following parasites of pigs:

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

* Includes somatic larval stages

The product may also be used as an aid in the control of adult whipworm (*Trichuris suis*).

4.3 Contra-indications

This product is not to be used intramuscularly or intravenously.

The product is formulated specifically for use in pigs only. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

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

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

(ii) Special precautions to be taken by the person administering the medicinal product to the animals

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 injection site.

4.6 Adverse reactions (frequency and seriousness)

Mild and transient discomfort has occasionally been observed in pigs following subcutaneous administration.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Studies have demonstrated a wide safety margin. At the recommended use level, no adverse effects on fertility or gestation in breeding animals were observed.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

At the recommended dosage level of 300 mcg ivermectin per kg of bodyweight, administer only subcutaneously in the neck in pigs.
Each ml contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs.

Use the following dosage table:

Bodyweight (kg)	Dose Volume (ml)	Doses Per Pack	
		200ml	500ml
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

The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 17 gauge x 1/2 inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals 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 broached more than 20 times.
In young pigs, especially those weighing under 16kg for which less than 0.5ml of the product is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver increments of 0.1ml is recommended. For piglets weighing less than 16kg give 0.1ml/3kg.

When treating pigs of less than 16kg seek veterinary advice regarding the use of 1ml disposable syringes graduated in increments of 0.1ml.

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 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 an important source of infestation of mange.
Treat at least twice a 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. Alternatively, control can be achieved by treating the whole herd at six monthly intervals.
Fatteners
Treat before placement in clean quarters.
Note (1) For effective mange control, care must be taken to prevent re-infestation 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, labored breathing and lateral recumbency.
No antidote has been identified; however, symptomatic therapy may be beneficial.

4.11 Withdrawal periods

Pigs. Meat: 19 days.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code:

QP54AA01

5.1 Pharmacodynamic properties

Mechanism of Action

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels, which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand gated chloride channels and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic properties

Maximum plasma concentration

During trials carried out at a dose rate of 0.2 mg/kg ivermectin, a plasma concentration of 10-20 ng/ml was reached in about 2 days and half-life in plasma was 0.5 days.

Excretion: length of time and route

A liquid chromatographic method with fluorescence detection allows the determination of ivermectin residues in tissues. After an injection of 0.4 mg/kg ivermectin the liver (target tissue) contained average residues ranging from 69 ppb at 3 days post dose to 13 ppb at 14 days post dose. No liver residue (< 2 ppb) was found at 28 days post dose. Swine receiving a single dose of tritium-labelled ivermectin (0.3-0.4 mg/kg) were slaughtered at 1, 7, 14 and 28 days after dosing. Composites of faeces collected during the first 7 days after dosing contained only about 36% of the dosed radioactivity. Less than 1% of the dosed radioactivity was found in the urine. Analysis of the faeces showed that about 40% of the excreted radioactivity was unaltered drug.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Formal
Propylene Glycol

6.2 Major incompatibilities

No major incompatibility has been identified.

6.3 Shelf-life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf-life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

Do not store above 30^0C.
Protect from direct sunlight.
Following withdrawal of the first dose, use the product within 6 months.
Discard unused material.

6.5 Nature and composition of immediate packaging

Multiple-dose rubber-capped polyethylene bottles of 100 ml, 200 ml, 500 ml and 1000 ml. Bottles are stoppered and then either sealed by heat or crimp-sealed with an aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4179

9. DATE OF FIRST AUTHORISATION

16 June 1993

10. DATE OF REVISION OF THE TEXT

October 2018

ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

Not applicable.

Approved 30 October 2018