Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

IVOMEC Injection for Pigs 10 mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
Ivermectin 10 mg

For a 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

IVOMEC Injection is indicated for the treatment and control of parasitic diseases of swine caused by the following parasites:

Gastrointestinal roundworms:
Ascaris suum (adults and fourth-stage larvae)
Hyostrongylus rubidus (adults and fourth-stage larvae)
Oesophagostomum spp. (adults and fourth-stage larvae)
Strongyloides ransomi (adults and somatic larval stages)

Lungworms:
Metastrongylus spp. (adults)

Lice:
Haematopinussuis

Mange mites:
Sarcoptes scabiei var. *suis*

IVOMEC Injection for Pigs may also be used as an aid in the control of adult **whipworm** (*Trichuris suis*).
IVOMEC Injection for Pigs given to sows 7 to 14 days before farrowing effectively controls transmission via the milk of *Strongyloides ransomi* infections to piglets.

NOTE
1. IVOMEC has a persistent drug level sufficient to control mite infections throughout the egg to adult life cycle. However, since the IVOMEC effect is not immediate care must be taken to prevent re-infestation from exposure to untreated animals or contaminated facilities. Generally pigs should be moved to clean quarters or exposed only to uninfected pigs for approximately one week after treatment.
2. Louse eggs are unaffected by IVOMEC and may require up to 3 weeks to hatch. Louse infestations developing from hatching eggs may require re-treatment.

4.3 Contraindications

This product is not for intravenous or intramuscular use.
Do not administer to animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
Ivomec Injection for Pigs has been formulated specifically for use in this target species. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not smoke or eat while handling the product.
Wash hands after use.
Take care to avoid self-administration; the product may cause local irritation and/or pain at the site of injection.

4.6 Adverse reactions (frequency and seriousness)

Mild and transient pain reactions may be seen in some pigs following subcutaneous administration.

4.7 Use during pregnancy, lactation or lay

IVOMEC Injection for Pigs can be administered to sows at any stage of pregnancy or lactation. IVOMEC Injection for Pigs will not affect the fertility of breeding sows and boars and can be given to all ages of animals including young piglets.

4.8 Interaction with other medicinal products and other forms of interaction

In vitro activity of ivermectin has been shown to be increased by benzodiazapine derivatives.

4.9 Amounts to be administered and administration route

Young animals and adults

IVOMEC Injection for pigs must be administered by subcutaneous injection in the neck, at the recommended dose rate of 1 ml per 33 kg body weight (corresponding to 0.3 mg ivermectin per kg bodyweight). The solution may be given with any standard automatic or single-dose equipment.
Use aseptic technique. To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

1. Breeding animals

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

SOWS:
Treat prior to farrowing, preferably 7-14 days before, to minimize infection of piglets.

GILTS:
Treat 7-14 days prior to breeding.
Treat 7-14 days prior to farrowing.

BOARS:
Frequency of and need for treatments are dependent upon exposure. Treat at least twice a year.

2. Growers/Finishers

All pigs received for finishing should be treated before placement in clean quarters. Pigs exposed to soil may need re-treatment if re-infection occurs.

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

A dose of 30 mg ivermectin per kg (100x 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 period(s)

Swine must not be treated within 14 days of slaughter for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides, avermectins
ATCvet code: QP54AA01

5.1 Pharmacodynamic properties

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 particulars

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 +/-2 days and the half-life in plasma was 0.5 day.
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

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage

Do not store above 25°C. Store bottle in carton box to protect from light.

6.5 Nature and composition of immediate packaging

Clear colourless solution presented in multiple-dose rubber-capped polyethylene bottles of 200ml and 500 ml. Not all pack sizes may be marketed.

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

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Do not contaminate lakes or streams as free ivermectin may adversely affect fish and certain water-borne organisms.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/066/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1999
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

May 2018