Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Premix for Pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Ivermectin 0.6% w/w

Excipients:

Fine ground corn cob.

For a full list of excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
Slightly yellow to brown fine fibrous meal mixture.

4 CLINICAL PARTICULARS

4.1 Target Species

Swine

4.2 Indications for use, specifying the target species

IVOMEC Premix for Pigs effectively controls the following parasites of swine when administered in the feed to provide the recommended dose level of 0.1 mg ivermectin per kg bodyweight daily for 7 days:

Gastrointestinal roundworms
Ascaris suum (adults and L4)
Hyostrongylus rubidus (adults and L4)
Oesophagostomum spp. (adults and L4)
Strongyloides ransomi (adults)*

Lungworms
Metastrongylus spp. (adults)

Lice
Haematopinus suis

Mange mites
Sarcoptes scabiei var. *suis*

*IVOMEC Premix given to pregnant sows before farrowing effectively controls transmission via milk of *S. ransomi* to piglets.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Exposure of treated pigs to infected animals, contaminated premises, soil or pasture may result in re-infection. Since the effect of ivermectin on mange mites is not immediate, avoid direct contact between treated and untreated pigs.

Since louse eggs may take up to three weeks to hatch, re-treatment may be necessary.

4.5 Special precautions for use

Special precautions for use in animals
No special precautions are required.

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.

4.6 Adverse reactions (frequency and seriousness)

No undesirable effects have been observed when the product is administered to swine at the recommended dose rate.

4.7 Use during pregnancy, lactation or lay

IVOMEC Premix for Pigs can be administered to sows at any stage of pregnancy or lactation. IVOMEC Premix for Pigs can be used in breeding sows and boars and will not affect fertility.

4.8 Interaction with other medicinal products and other forms of interaction

No incompatibilities with other commonly used products were observed.

4.9 Amounts to be administered and administration route

To ensure thorough dispersion of the product it should first be mixed with a suitable quantity of feed ingredients before incorporation in the final mix.

The recommended dose level is 100 mcg ivermectin/kg bodyweight fed daily for seven consecutive days. The appropriate inclusion rate of the premix, in grams per tonne of finished feed, can be calculated as follows:

Premix inclusion rate (g/tonne feed) = $\frac{100 \times \text{average bodyweight (kg)}}{6 \times \text{average daily feed intake (kg)}}$

Growing Pigs

The recommended dose level of 100 mcg/kg bodyweight daily for seven days is obtained under most circumstances, for pigs up to 40 kg bodyweight, by including 333g ivermectin premix in each metric tonne of final feed. The ivermectin should be thoroughly mixed in the finished feed and fed continuously as the only ration for seven consecutive days. In pigs weighing 40 kg liveweight and over, average daily feed consumption may fall below a feed intake of 5% where restricted feeding programmes are in use or where pigs are fed a ration high in protein.

For pigs weighing 40 kg and over, include 400g ivermectin premix in each metric tonne of final feed.

Adult Pigs

The recommended dose level for adult pigs weighing over 100 kg liveweight is achieved under most circumstances by thoroughly mixing 1.67 kg of IVOMEC Premix for Pigs with 1 tonne of swine ration. The resultant medicated feed is to be fed at the rate of 1 kg per 100 kg of bodyweight each day for seven consecutive days, as part of the individual ration. Where medicated feed is to be fed as part of the ration, it is recommended that the ivermectin medicated feed is fed first. After this is consumed, any remainder of the daily feed allocation should be provided. This should be repeated for seven consecutive days.

Alternatively, where dry feed intake can be accurately determined and all animals to be treated have similar bodyweight, the inclusion rate can be calculated using the previous formula to allow sole feeding of medicated feed.

RECOMMENDED TREATMENT PROGRAMME

Growing Pigs

Groups of growing pigs should be treated for seven consecutive days on transfer to clean quarters. Where an all-in all-out system is not possible, it is recommended that IVOMEC for Pigs in-feed parasite control programme should begin with treatment of all growing pigs already in the house.

Breeding animals: Breeding animals are treated by feeding medicated feed for seven consecutive days. At the time of initiating any parasite control programme, it is important to treat all animals in the herd. After the initial treatment, use IVOMEC Premix regularly as follows:

Sows: Treat, preferably 14-21 days, prior to farrowing, to minimise infection of piglets.

Gilts: Treat 14-21 days prior to breeding. Treat 14-21 days prior to farrowing.

Boars: Treat at least 2 times per year. Frequency of and need for treatments are dependent upon parasite exposure.

Note (1): Exposure of treated pigs to infected animals, contaminated premises, soil or pasture may result in re-infestation and re-treatment may be necessary.
Note (2): Since the effect of ivermectin on mange mites is not immediate, avoid direct contact between treated and untreated pigs for at least one week after completion of treatment.
Note (3): Since louse eggs are unaffected by ivermectin and may take up to three weeks to hatch, retreatment may be necessary.

When used as recommended, this product should only be incorporated by Category A manufacturers.

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

IVOMEC Premix for Pigs, included in the ration of pigs at levels up to 5 times the recommended dose of 0.1 mg ivermectin per kg bodyweight for 21 consecutive days (3 times the recommended treatment period), did not produce treatment-related adverse reactions. No antidote has been identified.

4.11 Withdrawal period(s)

Edible tissues from animals weighing less than 100 kg : 3 days.
Edible tissues from animals weighing more than 100 kg : 12 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

QP54AA01: ivermectin

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 particulars

Maximum plasma concentration
After administration of feed containing 2 ppm tritium-labelled ivermectin to swine at the recommended dose rate of 0.1 mg/kg/day, the plasma level of total ivermectin equivalents on-drug was 29.7 ppb. By 21 days off-drug, the mean plasma level was below 0.1 ppb.

Excretion: length of time and route
After administration of feed containing 2 ppm tritium-labelled ivermectin to swine at the recommended dose rate of 0.1 mg/kg/day, liver had the highest on-drug mean total residue level of 237.1 ppb, followed by fat, kidney and muscle at 207.2, 116.8 and 57.5 ppb, respectively. At 3 through 21 days off-drug, fat had the highest mean residue level. By 7 days off-drug mean total residue levels in liver, fat, kidney and muscle were 10.7, 18.0, 3.1 and 2.5 ppb, respectively. The muscle tissue generally contained the least residue. Accountability of dosed radioactivity in excreta collected 7 days on-drug and 21 days off-drug was 95.6 to 105.7%. Only 0.1 to 0.3% of the recovered radioactivity was in urine. The remainder was in the faeces. The majority of radioactivity was excreted by 3 days off-drug.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole
Propyl Gallate
Citric Acid
Propylene Glycol
Polyoxyl 40 Hydrogenated Castor Oil
Distilled Monoglycerides
Fine ground corn cob

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after incorporation into meal or pelleted feed: 3 months

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

5 kg and 25 kg multiwall paper bags with polyethylene inner liner.
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

Do not contaminate lakes and streams with unused product or waste material as free ivermectin may adversely affect fish and certain water borne organisms. Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time.
Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/067/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th June 1997
Date of last renewal: 12th June 2007

10 DATE OF REVISION OF THE TEXT

May 2018