SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVOMEC Premix for Pigs 0.6% Premix for Medicated Feed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient: Ivermectin 0.6% w/w

Formulated antioxidant: Butylated Hydroxyanisole; Propyl Gallate; Citric Acid; Propylene Glycol

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Premix for medicated feed

4. CLINICAL PARTICULARS

4.1 Target species

Swine.

4.2 Indications for use (specifying the target species)

The product 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

* Given to pregnant sows before farrowing, it effectively controls transmission via milk of *S. ransomi* to piglets.

4.3 Contraindications

Do not use for any other animal 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, including special precautions to be taken by the person administering the medicinal product to the animals

i. Special precautions for use in animals

None.

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.
Mixing of the product with feed must take place in a well ventilated area.
Avoid contact with skin and eyes. In case of accidental contact, wash the affected area thoroughly with clean running water. If eye irritation persists, seek medical advice.

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

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

No incompatibilities with other commonly used products were observed.

4.9 Amount(s) 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. Only to be mixed with dry feed.
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:

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

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 333 g 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 400 g 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 the premix 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 PROGAMME

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 the 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 the premix regularly as follows:

Sows: Treat, preferably 14-21 days, prior to farrowing, to minimize 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 three weeks to hatch, retreatment may be necessary.

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

The product can be incorporated in pelleted feed preconditioned with steam for up to 10 seconds at a temperature not exceeding 85^{o}C.

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

When 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), the product did not produce treatment related adverse reactions. No antidote has been identified.

4.11 Withdrawal period(s)

Pigs (over 100kg) : 12 days
Pigs (under 100kg) : 3 days

5. PHARMACOLOGICAL PROPERTIES

ATC Vet 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 properties

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

Polyoxyl 40 hydrogenated castor oil
Distilled monoglycerides
Citric acid anhydrous
Formulated antioxidant: butylated hydroxyanisole; propyl gallate; citric acid anhydrous; propylene glycol
Fine ground corn cob

6.2 Incompatibilities

No major incompatibility has been identified.

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°C. Store in a dry place.

6.5 Nature and composition of immediate packaging

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

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

Extremely dangerous to fish and aquatic life. Do not contaminate surface waters or ditches with the product or used container. Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4168

9. DATE OF FIRST AUTHORISATION

12 March 1992

10. DATE OF REVISION OF THE TEXT

October 2018

Approved 30 October 2018