Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetimec 6 mg/g Premix for medicated feeding stuff for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Ivermectin 6 mg/g

Excipient(s):
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff
Yellow-brown, free-flowing granules

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs.

4.2 Indications for use, specifying the target species

Treatment of nematode or arthropod infections due to:

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

Exposure of treated pigs to infected animals, contaminated premises, soil or pasture may result in re-infestation and re-treatment may be necessary. 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. Because louse eggs are unaffected by ivermectin and may take up to three weeks to hatch, re-treatment may be necessary.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Sick animals may have a reduced appetite and an altered drinking patterns and should, if necessary, individually monitored.

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to 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)

None known.

4.7 Use during pregnancy, lactation or lay

The product can be administered to sows at any stage of pregnancy or lactation.
This product can be used in breeding animals.
Use in lactating sows should be based on a risk-benefit assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

The effects of GABA agonists are increased by ivermectin.

4.9 Amounts to be administered and administration route

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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 0.1 mg ivermectin/kg bodyweight fed daily for seven consecutive days. The appropriate inclusion rate of the product, in grams per tonne of finished feed, can be calculated as follows:

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

In order to avoid under or overdosing, pigs to be treated should be grouped by weight and the dose to be administered should be calculated based on the heaviest animal in the group.

Growing Pigs
The recommended dose level of 0.1 mg/kg bodyweight daily for seven days is obtained under most circumstances, for pigs up to 40 kg bodyweight, by including 333 g product in each metric tonne of final feed. The product 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% of bodyweight 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 product 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 product in each metric 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 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 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.

This product should be incorporated by licensed feed manufacturers only.

The product can be incorporated in pelleted feed preconditioned with steam for up to 10 seconds at a temperature not exceeding 65^{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)

Meat and offal: 12 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide, 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

In a comparative blood study, after administration of the product to swine, at the recommended dose rate of 0.1 mg ivermectin per kg bodyweight for 7 consecutive days in diet, the mean plasma steady state concentration (Css) after the last dose was 4.45 ng/ml. The mean maximum plasma concentration (Cmax) after the last administration was 5.81 ng/ml occurring at (Tmax) approximately 5 hours after the last administration. Thereafter, mean plasma concentrations declined exponentially with the mean plasma half life (t½) up to 72 hours after the last dose representing 26 hours. By 120 hours after the last dose, mean plasma concentrations of ivermectin were below the limit of quantification of the assay in most animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl Gallate
Butylhydroxyanisole
Macrogolglycerol Hydroxystearate
Distilled Monoglyceride
Corn Cob

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after incorporation into feed: 8 weeks in meal and 4 weeks in pellets.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Store in a dry place.

6.5 Nature and composition of immediate packaging

333 g foil sachet
5.0 kg foil bag inside a polypropylene/paper laminate bag.
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

Extremely dangerous to fish and aquatic life. Do not contaminate surface waters or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

ECO Animal Health Europe Limited
6th Floor
South Bank House
Barrow Street
Dublin 4
D04 TR29
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22693/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 April 2015
Date of last renewal: 10 April 2020

10 DATE OF REVISION OF THE TEXT

February 2021