1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:

Ivermectin 6 mg

Excipients:

Qualitative composition of excipients and other constituents
Propyl gallate
Butylhydroxyanisole
Macrogolglycerol hydroxystearate
Distilled monoglyceride
Corn Cob

Yellow-brown, free-flowing granules.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each 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)*
*Given to pregnant sows before farrowing, it effectively controls transmission via milk of *S. ransomi* to piglets.

Lungworms
Metastrongylus spp. (adults)

Lice
Haematopinus suis

Mange mites
Sarcoptes scabiei var. *suis*

3.3 Contraindications

Do not use for any other animal species as severe adverse reactions, including fatalities in dogs may occur.

3.4 Special warnings

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 pattern and should, if necessary, be 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product.

Wash hands after use.

Mixing of the veterinary medicinal 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 and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.
Use in lactating sows only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:

Can be used in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by ivermectin.

3.9 Administration routes and dosage

Oral use.
For administration with feed.

This veterinary medicinal product should be incorporated by licensed feed manufacturers only.

The veterinary medicinal product can be incorporated in pelleted feed preconditioned with steam for up to 10 seconds at a temperature not exceeding 65 ºC.

Posology

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 veterinary medicinal 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 veterinary medicinal product, in grams per tonne of finished feed, can be calculated as follows:

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

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 veterinary medicinal 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 veterinary medicinal product did not produce treatment related adverse events.

No antidote has been identified.

If suspected adverse events occur, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

3.12 Withdrawal periods

Meat and offal: 12 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP54AA01.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

In a comparative blood study, after administration of the veterinary medicinal 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 (C_{ss}) after the last dose was 4.45 ng/ml. The mean maximum plasma concentration (C_{max}) after the last administration was 5.81 ng/ml occurring at (T_{max}) approximately 5 hours after the last administration. Thereafter, mean plasma concentrations declined exponentially with the mean plasma half-life ($t_{½}$) 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.
Store in a dry place.

5.4 Nature and composition of immediate packaging

Foil sachet
Pack sizes: 333 g.

Foil bag inside a polypropylene/paper laminate bag.
Pack sizes: 5.0 kg.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

ECO Animal Health Europe Limited.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22693/014/001

8. DATE OF FIRST AUTHORISATION

10/04/2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/08/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).