

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 6 mg/g Oral Powder for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:

Ivermectin: 6 mg

Excipients:

| Qualitative composition of excipients and other constituents | Quantitative composition if that information is essential for proper administration of the veterinary medicinal product |
|--|---|
| Butylhydroxyanisole (E320) | 1.0 mg |
| Propyl gallate (E310) | 0.3 mg |
| Macrogolglycerol hydroxystearate | |
| Distilled Monoglyceride | |
| Corn Cob | |

Yellow-brown, free-flowing granules.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and boars).

3.2 Indications for use for each target species

Treatment of nematode or arthropod infections due to:

Gastrointestinal roundworms

Ascaris suum (adults and L4)

Hyostromylus 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 in case of hypersensitivity to the active substance or to any of the excipients.

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

3.4 Special warnings

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.

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.

Use of the product deviating from the instructions given in the SPC might lead to an increased risk of development of resistance to ivermectin.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Exposure of treated pigs to infected animals, contaminated premises, soil or pasture may result in re-infestation and retreatment 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.

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 and show the package leaflet or the label to the physician.

Other precautions

Avermectins may not be well tolerated in non-target species as cases of intolerance have been reported in dogs especially Collies, old English sheepdogs and related breeds or crosses, and also in turtles/tortoises.

3.6 Adverse events

Pigs (sows and boars):

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.

Fertility:

Can be used in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

For administration with feed.

The veterinary medicinal product is to be administered only for the treatment of individually fed animals or a small group of animals where the intake by individual animals can be effectively controlled.

Posology:

The dosage is 0.1 mg ivermectin per kg bodyweight per day, corresponding to 16.7 mg product per kg bodyweight per day for 7 consecutive days.

The quantity for daily administration to individual pigs can be calculated using the formula: 16.7 mg Ecomectin per kg body weight per day x mean body weight (kg) of animals to be treated

Method of administration:

For use in individual animals (sows and boars) on farms where only a small number of pigs are to receive the medicine. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended. Larger groups should be treated with medicated feeding stuff manufactured using an appropriate anthelmintic premix.

It should be ensured that the recommended dose is completely taken.

Ivermectin should be mixed completely in a part of the feed ration before each treatment. It is recommended that ivermectin medicated feed is fed first, before offering the main ration to the animal.

Severely diseased animals with reduced appetite/anorexia should be treated parenterally.

The treatment schedule should be based on the local epidemiological situation.

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 product did not produce treatment related adverse reactions.

No antidote has been identified.

If suspected adverse reactions 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 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 ($t_{1/2}$) 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 first opening the immediate packaging: 28 days.

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

Heat-sealed aluminium foil sachet.

Pack size: 333 g.

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 is extremely dangerous to fish and aquatic life.

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)

VPA22693/013/001

8. DATE OF FIRST AUTHORISATION

22 October 2010

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

08/05/2026

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) (<https://medicines.health.europa.eu/veterinary>).

