Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 6 mg/g Oral Powder for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:		
Ivermectin	6	mg/g
Excipient(s):		
Butylhydroxyanisole (E320)	1.0	mg/g
Propyl gallate (E310)	0.3	mg/g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral powder.
Yellow-brown, free-flowing granules.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (sows and boars).

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 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.

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 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.

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 antelmintics 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.

4.5 Special precautions for use

Special precautions for use in animals
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.

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.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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 correct dosage, bodyweight should be determined as accurately as possible. Accurate and properly calibrated equipment should be used for weighing out the required amount of product.
Larger groups should be treated with medicated feeding stuff manufactured using an appropriate anthelmintic premix.

For oral administration with feed.
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.

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

4.11 Withdrawal period(s)

Meat and offal: 12 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide, macrocyclic lactones, avermectins, ivermectin
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

Macrogolglycerol hydroxystearate
Distilled Monoglyceride
Propyl Gallate
Butylhydroxyanisole
Corn Cob

6.2 Major incompatibilities

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

6.3 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

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

Pack size: 333 g
Composition: Aluminium foil sachet
Method of closure: Heat-sealed

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 material derived from such veterinary medicinal products 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)

VPA22693/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 October 2010
Date of last renewal: 02 October 2015

10 DATE OF REVISION OF THE TEXT

March 2019