SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 18.7 mg/g Oral Paste for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:
Active substance:
Ivermectin 18.7 mg

Excipient(s):
Titanium dioxide (E171) 20 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Paste
A white homogeneous paste

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

Treatment of nematode or arthropod infection due to:

Large strongyles:
Strongylus vulgaris (adults and L_4 stage larvae [arterial])
Strongylus edentatus (adults and L_4 stage larvae [tissue])
Strongylus equinus (adults)

Small strongyles (including benzimidazole resistant strains):
Cyathostomum spp (adults and luminal L_4 stage larvae)
Cylicocyclus spp. (adults and luminal L_4 stage larvae)
Cylicodontophorus spp. (adults and luminal L_4 stage larvae)
Cylicostephanus spp. (adults and luminal L_4 stage larvae)
Gyalocephalus spp. (adults and luminal L_4 stage larvae)

Ascarids:
Parascaris equorum (luminal L_5 larvae and adults)

Pinworms:
Oxyuris equi (L_4 stage larvae and adults)

Neck threadworms:
Onchocerca spp (microfilariae)

Stomach bots:
Gasterophilus spp (oral and gastric stages)

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs or cats as severe adverse reactions may occur.

4.4 Special warnings for each target species

Some horses with heavy infections of *Onchocerca* spp. microfilariae have experienced oedema and pruritus following treatment, such reactions are assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.
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 or misadministration of the product.

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. In the event that a product is suspected of being ineffective, the animal owner is advised to seek veterinary advice.

Resistance to ivermectin has been reported in *Parascaris equorum.* Therefore, the use of this product should be based on local farm epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics

4.5 Special precautions for use

Special precautions for use in animals

Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

Dogs and cats should not be allowed to ingest spilled gel or have access to used packaging due to the potential for adverse effects related to ivermectin toxicity

The product has been formulated for use in horses only. Cats, dogs (especially Collies, Old English Sheepdogs and related breeds or crosses) and also turtles and tortoises may be adversely affected by the concentration of ivermectin in this product if they are allowed to ingest spilled paste or have access to used syringes.

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

Do not smoke, eat or drink while handling the product.
Wash hands after use.

This product may cause skin and eye irritation. Therefore, the user should avoid contact of the product with the skin and the eyes. In case of contact, rinse immediately with plenty of water.
In the case of accidental ingestion or eye irritation after contact seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

The product can be administered to mares at any stages of pregnancy or lactation.
Do not use in mares producing milk for human consumption

4.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by ivermectin

4.9 Amounts to be administered and administration route

Dosage:
One syringe division of paste per 100 kg body weight (based on a recommended dosage of 200 µg ivermectin per kg body weight).
The syringe containing 6.42 g of paste delivers sufficient paste to treat 600 kg of bodyweight at the recommended dose rate.
The syringe containing 7.49 g of paste delivers sufficient paste to treat 700 kg of bodyweight at the recommended dose rate.

Administration:
The paste is given by oral route.

To ensure administration of a correct dose, body weight should be determined as accurately as possible. The animal's mouth should be free from food to ensure swallowing. Turn the screw gauge on the syringe plunger to the body weight of the horse. The tip of the syringe barrel should be inserted at the interdental space (the gap between the front and back teeth) and the paste deposited on the base of the

tongue. Advance the plunger as far as it will go, depositing the medication on the base of the tongue. Immediately elevate the horse's head for a few seconds to ensure swallowing.

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

Mild transitory signs (slowed pupillary light response and depression) have been seen at a higher dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis, ataxia, tremors, stupor, coma and death. The less severe signs have been transitory.

Although no antidote has been identified, symptomatic therapy may be beneficial.

4.11 Withdrawal period(s)

Meat and offal: 34 days
Do not use in mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide, macrocyclic lactones
ATCvet code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin is a member of the macrocyclic lactone class of endectocides. 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, which results 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 macrocyclic lactones do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic particulars

Following oral administration of the recommended dose to horses, a mean peak plasma concentration (Cmax) of 33 ng/ml was achieved within 24 hours.

Ivermectin is well absorbed into the systemic circulation following administration. Only about 2% of the drug is excreted in urine, faecal excretion being the major route of elimination.

Ivermectin passes readily into milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated Castor Oil
Hydroxypropylcellulose
Titanium Dioxide (E171)
Propylene Glycol

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
The product is for single use. After use, the syringe should be discarded.

6.4 Special precautions for storage

Do not store above 25ºC

6.5 Nature and composition of immediate packaging

High density polyethylene dose graduated syringes in an outer cardboard box.

Pack size:
Box containing 1 syringe of 6,42 g
Box containing 1 syringe of 7,49 g
Box containing 50 syringes of 7,49 g

Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ECO Animal Health Ltd.
The Grange
100 High Street
London
N14 6BN
United Kingdom

8. MARKETING AUTHORISATION NUMBER

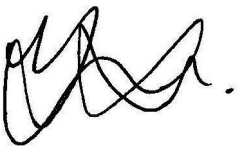
Vm 13277/4027

9. DATE OF FIRST AUTHORISATION

18 July 2013

10. DATE OF REVISION OF THE TEXT

June 2023



Approved: 01 June 2023