

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10850/005/001**

Case No: 7007538

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Virbac De Portugal Laboratorios

Rua Dionisio Saraiva, Lote 1, 1 Andar, Porta 2, Portugal

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Equimel 18.7 mg/g oral paste

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless revoked, shall continue in force from **01/04/2010** until .

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIMEL 18.7 mg/g ORAL PASTE

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g contains:

Active Substance:

Ivermectin 18.7 mg.

Excipients:

Titanium dioxide E171 as a colouring agent, Hydrogenated castor oil, Hydroxypropylcellulose and Propylene glycol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral paste.

White and thick paste.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

Roundworms in the stomach and intestines.

Large strongyles:

Strongylus vulgaris: adults and 4th larval (arterial) stages

Strongylus edentatus: adults and 4th larval (tissue) stages

Strongylus equinus: adults

Small strongyles, adults:

Cyathostomum spp.

Cylicocyclus spp.

Cylicodontophorus spp.

Cylicostephanus spp.

Gyalocephalus spp.

Hairworms:

Trichostrongylus axei: adults

Pinworms:

Oxyuris equi: adults and immatures

Ascarids:

Parascaris equorum: adults

Intestinal threadworms:

Strongyloides westeri: adults

Large-mouth stomach worms:

Habronema muscae: adults

Neck threadworms:

Onchocerca spp. (microfilariae)

Lungworms:

Dictyocaulus arnfieldi: adult and immature

Stomach bots:

Gasterophilus spp.: oral and gastric larval stages

4.3 Contraindications

Not permitted for use in mares producing milk for human consumption.

Do not use in dogs or cats as severe adverse reactions may occur.

Do not use in case of known hypersensitivity to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Avermectins may not be well tolerated in all non-target species (cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

As ivermectin is extremely dangerous to fish and aquatic life treated animals should not have direct access to surface water and ditches during treatment.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

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.

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

Do not eat, drink or smoke while handling the product. Avoid contact with skin and eyes. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and, if necessary, get medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Some horses carrying heavy infection of *Onchocerca* microfilariae have experienced reactions with swelling and itching following dosing, 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.

4.7 Use during pregnancy, lactation or lay

Can be used in pregnant mares.

Not permitted for use in mares producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Posology

A single administration of 200 µg ivermectin per kg of bodyweight.

Each syringe division mark plunger delivers enough paste to treat 100 kg of bodyweight (which corresponds to 1.07 g of product and 20 mg of ivermectin).

The syringe containing 6.42 g of paste delivers sufficient paste to treat 600 kg of bodyweight at the recommended dose range.

The syringe containing 7.49 g of paste delivers sufficient paste to treat 700 kg of bodyweight at the recommended dose range.

Directions for use

Horse weight should be accurately determined for the correct use of the paste. The animal's mouth should be free of food. The syringe must be positioned between the front and back teeth and the paste must be placed on the base of the horse's tongue. Immediately elevate the head of the horse for a few seconds to ensure deglutition.

Re-treatment should be done according to the epidemiological situation, but not at less than 30 days interval.

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: 30 days.

Not permitted for use in mares producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Avermectins

ATCvet code: QP 54 AA 01

Ivermectin belongs to the avermectin class of anthelmintics.

5.1 Pharmacodynamic properties

Ivermectin is a macrocyclic lactone derivative and acts by inhibiting nerve impulses. It binds 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 relevant parasites. 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 properties

After oral administration of the recommended doses to horses, the following parameters were observed: C_{max} of 48.79 ng/ml, T_{max} of 5.5 hours, elimination half-life of 61 hours. Ivermectin is eliminated primarily via the faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening of the container: 6 months.

6.4 Special precautions for storage

Do not store above 30°C.
Store in the original packaging.

6.5 Nature and composition of immediate packaging

The product is presented in 6.42 g or 7.49 g plastic syringes made from polyethylene and graduated in 100 kg body weight graduations.

Product presentations:

6.42 g syringe:
Box of 1, 12 or 48 syringes.
Blister of one syringe.

7.49 g syringe:
Box of 1, 12 or 48 syringes.
Blister of one syringe.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements. Ivermectin is extremely dangerous to fish and aquatic life. Do not contaminate surface water or ditches with the product or used containers.

7 MARKETING AUTHORISATION HOLDER

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Rua Dionisio Saraiva , Lote 1, 1º Andar, Sala 2
2080 –104 Almeirim - PORTUGAL

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10850/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th June 2005

10 DATE OF REVISION OF THE TEXT

15th March 2006