

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAQUELL 18.7 mg/g Oral Paste

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active Substance:

Ivermectin 18.7 mg.

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Titanium dioxide (E171)	0.02 g
Hydrogenated castor oil	
Hydroxypropylcellulose	
Propylene glycol	

White and thick paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each 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

3.3 Contraindications

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

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

See also section 3.12 “Withdrawal periods”.

3.4 Special warnings

Strategies that should be avoided because they might lead to an increased risk of development of resistance to anthelmintic drugs include:

- 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. 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.

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

As with all anthelmintics, a veterinary surgeon should establish appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance.

Special precautions to be taken by the person administering the veterinary 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.

Special precautions for the protection of the environment:

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

Other precautions:

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).

3.6 Adverse events

Horses:

Undetermined Frequency (cannot be estimated from the available data)	Swelling* Itching*
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*For some horses carrying heavy infection of *Onchocerca* microfilariae and 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.

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used in pregnant mares.

See also section 3.12 “Withdrawal periods”.

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.

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 veterinary medicinal 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:

To ensure a correct dosage, body weight should be determined as accurately as possible. 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.

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

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.

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

Not applicable.

3.12 Withdrawal periods

Meat and offal : 30 days.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP 54 AA 01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life after first opening of the immediate packaging: 6 months.

5.3 Special precautions for storage

Do not store above 30°C.

Store in the original package.

5.4 Nature and composition of immediate packaging

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

Pack sizes:

6.42 g syringe:

Box of 1, 2, 12, 40 or 48 syringes.

Transparent PVC blister sealed onto a carton sheet containing one syringe

7.49 g syringe:

Box of 1, 2, 12, 40 or 48 syringes.

Transparent PVC blister sealed onto a carton sheet containing one syringe

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 for fish and other aquatic organisms.

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

Do not contaminate surface water or ditches with the veterinary medicinal product or used containers.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Virbac S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10988/104/001

8. DATE OF FIRST AUTHORISATION

15 April 2016

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

25 April 2024

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>).