# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAQUELL 18.7 mg/g Oral Paste

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active Substance:**
Ivermectin ..... 18.7 mg/g.

**Excipients:**
Titanium dioxide (E171) ..... 0.02 g/g.
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 4$^{th}$ larval (arterial) stages
*Strongylus edentatus:* adults and 4$^{th}$ 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 Contra-indications

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.
See also section 4.11 “Withdrawal periods”.

## 4.4 Special warnings for each target species

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 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.

## 4.5 Special precautions for use

i. Special precautions for use in animals

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.
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.

ii. 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.

## 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.
See also section 4.11 “Withdrawal periods”.

## 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

**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.
Do not use in mares producing milk for human consumption.

# 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide, macrocyclic lactones.

ATCvet code : QP 54 AA 01

## 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 particulars

After oral administration of the recommended doses to horses, the following parameters were observed: Cmax of 48.79 ng/ml, Tmax 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

Titanium dioxide E171
Hydrogenated castor oil
Hydroxypropylcellulose
Propylene glycol

## 6.2 Incompatibilities

Not applicable.

## 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, 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.

## 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Ivermectin is extremely dangerous to fish and aquatic life. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product

should be disposed of in accordance with local requirements. Do not contaminate surface water or ditches with the product or used containers.

## 7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

## 8. MARKETING AUTHORISATION NUMBER

Vm 05653/5043

## 9. DATE OF FIRST AUTHORISATION

16 November 2000

## 10. DATE OF REVISION OF THE TEXT

October 2024

*Gavin Hall*
Approved: 23 October 2024