

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Eraquell Tabs, 20 mg Chewable tablets for Horses

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet of 3300 mg contains:

### Active substance

Ivermectin 20 mg

### Excipients

For full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Chewable tablet.

White, circular, biconcave tablet with brown spots.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Horses.

### 4.2 Indications for use, specifying the target species

For the treatment of nematode and arthropod infestations, due to adult and immature roundworms and bots in horses:

#### ◆ Nematodes

##### Large-strongyles:

*Strongylus vulgaris* (adult and arterial larvae)

*Strongylus edentatus* (adult and L4 tissue larval stages)

*Strongylus equinus* (adult and L4 larval stage)

*Triodontophorus* spp. (adult)

##### Small-strongyles:

Cyathostomum (adult and non-encysted mucosal larvae): *Cylicocyclus* spp., *Cylicostephanus* spp., *Gyalocephalus* spp.

Parascaris: *Parascaris equorum* (adult and larvae).

Oxyuris: *Oxyuris equi* (adult and larvae).

Trichostrongylus: *Trichostrongylus axei* (adult).

◆ **Dipteran insects:** *Gasterophilus* spp. (larvae).

### 4.3 Contraindications

Do not use in foals under 2 weeks of age.

Do not use in horses known to be hypersensitive to the active ingredient or any of the other ingredients.

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

#### 4.4 Special warnings for each target species

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 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.

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.

The product is safe for use in stallions.

Young foals, miniature horses and toy breeds weighing less than 50 kg may be unable to ingest tablets. Seek the advice of your veterinary surgeon.

#### 4.5 Special precautions for use

##### Special precautions for use in animals

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 tablets or have access to used packaging. (see 4.3).

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

Wash hands after use.

Avoid contact with the eyes. In the event of accidental contact with the eyes, rinse immediately with plenty of water. In case of eye irritation, seek medical attention.

Do not eat, drink or smoke while handling this product.

In the event of accidental ingestion, seek medical advice and show the package leaflet to the physician.

#### 4.6 Adverse reactions (frequency and seriousness)

Colic, diarrhoea and anorexia have been reported in very rare occasions post treatment, in particular when there is heavy worm burden. In very rare occasions, allergic reactions such as hypersalivation, lingual oedema, urticaria, tachycardia, congested mucus membranes, and subcutaneous oedema have been reported following treatment with the product.

#### 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

#### 4.8 Interaction with other medicinal products and other forms of interaction

None known.

#### 4.9 Amounts to be administered and administration route

Single oral administration.

200 µg of ivermectin per kg of bodyweight corresponding to 1 tablet per 100 kg bodyweight.

Weight	Dosage	Weight	Dosage
Up to 100 kg	1 tablet	401-500 kg	5 tablets
101-200 kg	2 tablets	501-600 kg	6 tablets
201-300 kg	3 tablets	601-700 kg	7 tablets
301-400 kg	4 tablets	701-800 kg	8 tablets

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

Once the correct dose has been determined, it should be administered in the following way :

Present the tablet in the palm of your hand.

Presenting one tablet at a time makes it easier for the horse to accept it, however the administration of multiple tablets at once is also possible.

Repeat this gesture until the complete dose has been administered.

During the initial administration, the tablet can be combined with a small amount of food or a treat to increase the acceptance by the horse.

In the event that the required dose is not ingested an alternative treatment should be administered. Seek the advice of your veterinary surgeon.

The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control for both roundworm and bot infestations.

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

A tolerance study performed with the product in adult horses with doses up to 5 times the recommended dosage did not show any adverse reactions.

Safety studies were conducted with a veterinary medicinal product containing praziquantel and the same dose of ivermectin (EQUIMAX oral gel), in mares, stallions and foals.

Administration to mares at 3 times the recommended dosage at 14-day intervals during the whole gestation and lactation periods did not result in any abortion, nor any adverse effect during gestation, at parturition or on the mares general health, nor any abnormality in the foals.

Administration to stallions at 3 times the recommended dosage did not show any adverse effect in particular on the reproductive performances.

Administration to foals with doses up to 5 times the recommended dosage did not show any adverse reaction.

#### 4.11 Withdrawal Period(s)

Meat and offal: 35 days.

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

### 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides, Avermectins.

ATCvet code: QP 54AA01

## 5.1 Pharmacodynamic properties

Ivermectin is a macrocyclic-lactone derivative which has a broad antiparasitic activity against nematodes and arthropods. It acts by inhibiting nerve impulses. Its mode of action includes the glutamate-gated chloride ion channels. Ivermectin 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 hyperpolarisation 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 high margin of safety for compounds of this class is attributable to the fact that, in mammals, glutamate receptors in chloride ion channels do not occur; the macrocyclic lactones have a low affinity to other mammalian ligand-gated chloride ion channels and they do not readily cross the blood-brain barrier.

## 5.2 Pharmacokinetic properties

After oral administration of the product at the recommended dosage to horses, the ivermectin peak plasma concentration of around 14 ng/mL ( $C_{\max}$ ) was reached at a  $T_{\max}$  of  $9 \pm 6$  hours. and the oral mean absolute bioavailability of ivermectin is around 16%.

The terminal half-life varies between 2 and 5 days after various routes of administrations. Ivermectin is a poorly metabolised compound. Due to its lipophilic nature, ivermectin is excreted in bile and ultimately eliminated from the body via the faeces. In horses, about 75% of the administered dose is excreted via the faeces after an oral administration of ivermectin at the recommended dose. Moreover 90% of the total drug is excreted within 4 days post-administration. Approximately 2% of unchanged ivermectin and metabolites are excreted in urine.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Povidone  
Crospovidone  
Cellulose, microcrystalline  
Cider Applemarc (pressed apple pulp)  
Glucose, liquid  
Starch, pregelatinised (maize starch)  
Compressible sugar  
Magnesium stearate

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 1 year.

### 6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage condition.

## **6.5 Nature and composition of immediate packaging**

Carton box containing 1, 2, 12, 40 or 48 polypropylene tubes of 8 tablets closed by a polyethylene child proof cap.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. **EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.** Do not contaminate surface waters or ditches with the product or used container.

## **7 MARKETING AUTHORISATION HOLDER**

Virbac  
1<sup>ère</sup> Avenue –2065 m L.I.D  
06516 Carros  
Cedex  
France

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA: 10988/077/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 2<sup>nd</sup> October 2009

Date of last renewal: 22<sup>nd</sup> August 2014

## **10 DATE OF REVISION OF THE TEXT**