

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax Tabs 150 mg / 20 mg Chewable tablet for Horses.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet of 3300 mg contains:

Active substances

Ivermectin 20 mg

Praziquantel 150 mg

For a 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 mixed cestode, nematode and arthropod infestations, due to adult and immature roundworms, lungworms, bots and tapeworms 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).

◆ **Cestodes (Tapeworm):** *Anoplocephala perfoliata* *Anoplocephala magna*, *Paranoplocephala mamillana*

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

As tapeworm infestation is unlikely to occur in horses before two months of age, treatment of foals below this age is not considered necessary.

4.3 Contraindications

Do not use in foals under 2 weeks of age.

Do not use in horses producing milk for human consumption.

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

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 tablets.

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 in a number of countries including ones in the EU. Therefore the use of this product should be based on national (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics

The product can be used safely in stallions.

4.5 Special precautions for use

Special precautions for use in animals

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.

Avermectins may not be well tolerated in non target species. Cases of intolerance are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles and tortoises.

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

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 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 case of accidental ingestion, seek medical advice immediately 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 and urticaria, tachycardia, congested mucus membranes, and subcutaneous oedema have been reported following treatment with the product.

4.7 Use during pregnancy, lactation or lay

Equimax tabs can be administered to horses at any stage of pregnancy or lactation.

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

Single oral administration.

200 µg of ivermectin and 1.5 mg of praziquantel per kg of bodyweight corresponding to 1 tablet per 100 kg bodyweight.

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

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

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

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

4.11 Withdrawal Period(s)

Horses : Meat and offal: 35 days.

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides, ivermectin, combinations.

ATCvet code: QP 54AA51

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 margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels.

Praziquantel is a pyrazinoisoquinoline derivative which exerts its anthelmintic activity against many species of Cestodes and Trematodes. It primarily acts by impairing both motility and function of the suckers of cestodes. Its mode of action includes the impairing of neuromuscular co-ordination but also influencing the permeability of the integument of the worms, which leads to excessive calcium and glucose loss. This induces spastic paralysis of the parasite musculature.

5.2 Pharmacokinetic properties

After oral administration at the recommended dosage, the ivermectin peak plasma concentration of around 12 ng/mL (C_{max}) was reached between 4 and 8 hours (T_{max}). The oral mean absolute bioavailability of ivermectin is around 9%.

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.

Orally, praziquantel is rapidly absorbed, and then rapidly undergoes a strong first pass effect in all the species studied. After oral administration at the recommended dosage, the mean maximal praziquantel concentration of around 0.3 µg/mL (C_{max}) is reached in a range of 0.2-2 hours (T_{max}). The oral mean absolute bioavailability of praziquantel is around 36%. Praziquantel is a compound rapidly distributed in body tissues due to its high lipid solubility; the radioactivity tends to be localised mainly in the excretion organs, i.e. liver and kidneys. Praziquantel is an extensively metabolised compound in animals. The excretion occurs mainly via urine (approximately 70-80%) within 24 h as a variety of metabolites.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale : 30 months

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 conditions.

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 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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the 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

VIRBAC

1^{ière} Avenue

2065 m, L.I.D,

06516 Carros,

Cedex,

France

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10988/070/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th June 2013

10 DATE OF REVISION OF THE TEXT