SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax Oral Gel for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Equimax contains

Active substances
Ivermectin ..... 18.7 mg
Praziquantel ..... 140.3 mg

Excipients
Titanium dioxide (E171) ..... 20 mg
Propylene glycol ..... 731 mg

For a full list of excipents, see section 6.1

3. PHARMACEUTICAL FORM

Oral gel.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

For the treatment of mixed cestode and nematode or arthropod infestations, due to adult and immature roundworms, lungworms, bots and tapeworms in horses:

♦ **Nematodes**
Large-strongyle:
Strongylus vulgaris (adult and arterial larvae)
Strongylus edentatus (adult and L4 tissue larval stages)
Strongylus equinus (adult)
Triodontophorus spp. (adult)

Small-strongyle:
Cyathostomum*:* *Cylicocyclus* spp.*,* *Cylicostephanus* spp., *Cylicodontophorus* spp., *Gyalocephalus* spp. (adult and non-inhibited mucosal larvae).

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

Oxyuris: *Oxyuris equi* (larvae).

Trichostrongylus:*Trichostrongylus axei* (adult).

Strongyloides: *Strongyloides westeri* (adult).

Habronema: *Habronema* spp. *(*adult*),*

Onchocerca: *Onchocerca* spp. microfilariae i.e. cutaneous onchocerciasis

Lungworm: *Dictyocaulus arnfieldi* (adult and larvae).

- **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 mares from which milk is taken for human consumption.

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

4.4 Special warnings for each target species

The product can be used safely in stallions.

Care should be taken to avoid the following practices because they increase the risk of the 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 (an avermectin) has been reported in *Parascaris equorum* in horses in a number of countries including the EU. 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 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 paste or access to used syringes due to the potential for adverse effects related to ivermectin toxicity.

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

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

Wash hands after use (to be sure that eye contamination can not occur).
Avoid contact with the eyes. In the case of accidental contact, rinse with abundant quantities 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 doctor the leaflet so that he knows what you have taken.

4.6 Adverse reactions (frequency and seriousness)

Horses carrying heavy infection of *Onchocerca microfilariae* have experienced such reactions as swelling and itching after treatment. It is assumed that these reactions are the result of the destruction of large numbers of microfilariae.

In case of very high levels of infestation, destruction of the parasites may cause a mild transient colic and loose faeces in the treated horse.

Colic, diarrhea and anorexia have been reported in vary 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.

A veterinarian should be consulted if these signs persist.

4.7 Use during pregnancy, lactation or lay

The product can be used safely in mares during the whole pregnancy period and lactation period.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Posology
Single administration.
200 µg of Ivermectin and 1.5 mg of praziquantel per kg of bodyweight corresponding to 1.07 g of paste per 100 kg bodyweight.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked as underdosing might lead to an increased risk of development of resistance to anthelmintic drugs.

Weight	Dosage	Weight	Dosage
Up to 100 kg	1.070 g	401-450 kg	4.815 g
101-150 kg	1.605 g	451-500 kg	5.350 g
151-200 kg	2.140 g	501-550 kg	5.885 g
201-250 kg	2.675 g	551-600 kg	6.420 g
251-300 kg	3.210 g	601–650 kg*	6.955 g
301-350 kg	3.745 g	651-700 kg*	7.490 g
351-400 kg	4.280 g		

* Concerns the 7.49g syringe only

The first division delivers enough paste to treat 100 kg.
Each subsequent syringe division delivers enough paste to treat 50 kg of bodyweight. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger.

The syringe containing 6.42 g of paste delivers sufficient paste to treat 600 kg of bodyweight at the recommended dose rate.
The syringe containing 7.49 g of paste delivers sufficient paste to treat 700 kg of bodyweight at the recommended dose rate.

Directions for use

Oral use

Before administration, adjust the syringe to the calculated dosage by setting the ring on the plunger. The paste is administered orally by inserting the nozzle of the syringe through the interdental space and depositing the required amount of paste on the back of the tongue. The animal's mouth should be free of any food. Immediately after administration, elevate the head of the horse for a few seconds to ensure the dose is swallowed.

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 from 2 weeks of age with doses up to 5 times the recommended dosage showed no adverse reactions.

Safety studies conducted with the veterinary medicinal product administered to mares at 3 times the recommended dosage at 14 day intervals during the whole gestation and lactation did not show any abortions, any adverse effects on the gestation, parturition and on the mares general health, nor any abnormalities on the foals.

Safety studies conducted with the veterinary medicinal product administered to stallions at 3 times the recommended dosage did not show any adverse effects in particular on the reproductive performances.

4.11 Withdrawal period(s).

In Horses: Meat and Offal: 35 days
Not permitted for use in horses producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics
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 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.

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 particulars

After administration of the recommended dosage to horses, the ivermectin plasma peak was reached within 24 hours. The ivermectin concentration was still over 2 ng/ml 14 days after administration. The elimination half-life of ivermectin was 90h. With regard to praziquantel, the plasma peak was reached within 1 hour. The praziquantel was rapidly eliminated and was not detected after 8 h post treatment. The elimination half-life of praziquantel was 40 min.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated castor oil
Hydroxypropylcellulose
Titanium dioxide (E171)
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 the immediate packaging: 6 months.

6.4 Special precautions for storage

Do not store above 30°C. Store opened syringes below 25°C.

6.5 Nature and composition of immediate packaging

An adjustable multidose syringe consisting of high density polyethylene (white) and low density polyethylene (white). The syringe contains 6.42 or 7.49 grams of product and is fitted with variable dose capacity.

Product presentations:
Box of 1, 2, 12, 40 or 48 syringes.
Blister of one syringe.

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

Any unused product or waste material should be disposed of in accordance with national 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
1ére Avenue 2065m L.I.D.
06516 Carros Cedex
France

8. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5042

9. DATE OF FIRST AUTHORISATION

06 July 2001

10. DATE OF REVISION OF THE TEXT

April 2024