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, diarrhoea and anorexia have also been reported in published studies

in very rare occasions post-treatment, in particular when there is heavy worm

Rarely, allergic reactions such as hypersalivation, lingual oedema and urticaria, tachycardia, congested mucus membranes, and subcutaneous oedema have been reported in published studies following treatment with ivermectin and praziquantel oral paste.

A veterinarian should be consulted if these signs persist. There have been published study reports of swelling and irritation of the mouth, lips and tongue following administration of ivermectin and praziguantel oral paste. These reactions have been transitory in nature.

OVERDOSAGE

A published tolerance study performed in foals from 2 weeks of age with doses up to five times the recommended dosage showed no adverse

Published safety studies conducted with ivermectin and praziquantel oral paste administered to mares at three times the recommended dosage at 14-day intervals during the whole gestation and lactation period did not show any abortions, any adverse effects on the gestation, parturition and on the mares' general health, nor any abnormalities in the foals.

Published safety studies conducted with ivermectin and praziquantel oral paste administered to stallions at three times the recommended dosage did not show any adverse effects in particular on the reproductive performance.

INCOMPATIBILITY

Not applicable

STORAGE

Store below 30°C

Discard after 6 months from the date of first use.

FOR ANIMAL TREATMENT ONLY NOT FOR HUMAN USE FOR VETERINARY ONLY

KEEP OUT OF REACH OF CHILDREN & PETS, AWAY FROM FOOD

Use as directed by a registered veterinary practitioner.

PACKAGING INFORMATION Kick Tape Equine oral paste

One Syringe of 6.42 gms



Manufactured & Marketed by: Veko Care Pvt. Ltd.
Plot No. E-48 & 49,
MIDC, Ranjangaon, Dist-Pune.
Maharashtra, India.
Pin Code: 412220

For the use of a Registered Veterinary Practitioner or a Hospital or a Laboratory only

IVERMECTIN AND PRAZIQUANTEL ORAL PASTE

Kick TAPE™- Equine Oral Paste

COMPOSITION

Each gram contains:

Excipients.....

DOSAGE FORM

Oral paste PHARMACOLOGY

Ivermectin is a macrocyclic-lactone derivative, which has a broad anti-parasitic 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 glutamategated 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.

Pharmacokinetics

Published studies reported that after administration of the recommended dosage to horses, the ivermectin plasma peak concentration 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 90 hours. With regard to praziquantel, the plasma peak was reached within 1 hour. Praziquantel was rapidly eliminated and was not detected after 8 hours post-treatment. The elimination half-life of praziquantel was 40 minutes

INDICATIONS 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

<u>Cyathostomum</u>: 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

<u>Dipteran Insects</u>: Gasterophilus spp. (larvae)

As tapeworm infestation is unlikely to occur in horses before 2 months of age, treatment of foals below this age is not considered necessary.

DOSAGE AND ADMINISTRATION

Single Administration: 200 µg of ivermectin and 1.5 mg of praziquantel per kg of body weight corresponding to 1.07 g of paste per 100 kg body weight. 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.

3			
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		
301-350 kg	3.745 g		
351-400 kg	4.280 a		

The first division delivers enough paste to treat 100 kg of body weight.

Each subsequent syringe division delivers enough paste to treat 50 kg of body weight. 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 body weight at the recommended dose rate.

Directions for 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 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.

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.

WARNINGS AND PRECAUTIONS

Ivermectin and praziquantel oral paste 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, mis-administration of ivermectin and praziquantel oral paste, 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. Therefore, the use of ivermectin

and praziquantel oral paste 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.

Drug Interactions

Pregnancy and Lactation

Ivermectin and praziquantel oral paste can be used safely in mares during the whole pregnancy period and lactation period.

Withdrawal Period(s)
In Horses: Meat and Offal: 35 days

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

Special Precautions for Use in Animals

Ivermectin and praziquantel oral paste has been formulated specifically for use in horses **only** and should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result. Ivermectins 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

Parasite resistance to a particular class of anthelmintics may develop

following frequent, repeated use of an anthelmintic of that class 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 cannot 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 ivermectin and praziquantel oral

In the event of accidental ingestion, seek medical advice and show the doctor the leaflet so that he/she knows what you have taken

UNDESIRABLE EFFECTS

Published studies have reported that horses carrying heavy infection of Onchocerca micorfilariae have experienced reactions as swelling and itching after treatment. It is assumed that these reactions are the result of the destruction of large numbers of microfilariae.

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