Equimax Tabs

Introduction

Company name: Virbac Limited
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Presentation

White, circular, biconcave tablet with brown spots.
Each chewable tablet of 3300 mg contains:
Ivermectin 20mg
Praziquantel 150mg

Uses

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.

Ascarids
Parascaris equorum (adult and larvae).

Pinworms
Oxyuris equi (adult and larvae).

Hairworms
Trichostrongylus axei (adult)

Cestodes (Tapeworm):
Anoplocephala perfoliata,Anoplocephala magna, Paranoplocephala mamillana
As tapeworm infestation is unlikely to occur in horses before two months of age, treatment of foals below this age is not considered necessary.

Stomach Bots
Gasterophilus spp. (larvae).

Dosage and administration

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

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

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 b 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.
Advice regarding appropriate dosing programmes and stock management should be sought to achieve adequate parasite control for both tapeworm and roundwor

infestations.

Contra-indications, warnings, etc

For animal treatment only.

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 the active ingredients or any of the other ingredients.

Special warnings for 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.

Can be used during pregnancy and lactation.

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 tablets or have access to used packaging due to the potential for adverse effects related to ivermectin toxicity.

Operator Warnings

Wash hands after use. Avoid contact with the eyes. In case of eye irritation, seek medical attention. Do not eat, drink or smoke while handling this product. Keep out of the reach of children. In the event of accidental ingestion, seek medical advice and show the leaflet to the physician so that he knows what you have taken.

Adverse reactions

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.

Withdrawal Period

Horses may be slaughtered for human consumption only after 35 days from the last treatment.

Container Disposal

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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.

Pharmaceutical precautions

Keep out of reach and sight of children. Do not store above 30°C

Shelf life of the veterinary medicinal product as packaged for sale : 18 months

Shelf life after first opening the immediate packaging : 12 months

Legal category

POM-VPS

Packaging Quantities

Carton box containing 12 polypropylene tubes of 8 tablets, sufficient to treat 800 kg of bodyweight, closed by a child proof cap.

Further information

No known interaction with other equine medicaments.

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

Safety studies conducted with a similar veterinary medicinal product (EQUIMAX oral gel) administered to mares at 3 times the recommended dosage at 14-day intervals during the whole gestation and lactation periods did not result in any abortions, nor any adverse effects during gestation, at parturition or on the mares general health, nor any abnormalities in the foals.

Safety studies conducted with a similar veterinary medicinal product (EQUIMAX® oral gel) administered to stallions at 3 times the recommended dosage did not show any adverse effects in particular on the reproductive performances.

Marketing authorisation number

VM05653/4142.

Significant Changes

Equimax Tabs	Virbac Limited	New Product	05/09/2008