Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

EQVALAN Oral Paste for Horses 18.7 mg/g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active Substance:
Ivermectin 18.7 mg

Excipients:
Titanium dioxide (E171) 20.0 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral paste.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the target species

EQVALAN Paste is indicated for the treatment of parasitic infestations in horses due to:

Large strongyles

Strongylus vulgaris (adults and arterial larval stages)
S. edentatus (adults & tissue larval stages)
S. equinus (adults)
Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus
Triodontophorus tenuicollis
Craterostomum acuticaudatum (adults)

Small Strongyles Adult and lumenal immature stage small strongyles or cyathostomes, including benzimidazole-resistant strains:

Coronocyclus spp.
Coronocyclus coronatus
Coronocyclus labiatus
Coronocyclus labratus
Cyathostomum spp.
Cyathostomum catinatum
Cyathostomum pateratum
Cylicocyclus spp.
Cylicocyclus ashworthi
Cylicocyclus elongatus
Cylicocyclus insigne

Cylicocyclus leptostomum
Cylicocyclus nassatus
Cylicocyclus radiatus
Cylicostephanus spp.
Cylicostephanus asymetricus
Cylicostephanus bidentatus
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus
Cylicodontophorus spp.
Cylicodontophorus bicornatus
Gyalocephalus capitatus
Parapoteriostomum spp
Parapoteriostomum euproctus
Parapoteriostomum mettami
Petrovinema spp
Petrovinema poculatum
Poteriostomum spp
Poteriostomum imparidentatum
Poteriostomum ratzii

Lungworms (adult & immatures)
Dictyocaulus arnfieldi

Pinworms (adult & immatures)
Oxyuris equi

Ascarids (adults & immatures)
Parascaris equorum

Hairworms (adults)
Trichostrongylus axei

Large-mouth stomach worms (adults)
Habronema muscae

Neck threadworms (microfilariae)
Onchocerca spp.

Intestinal threadworms (adults)
Strongyloides westeri

Stomach bots
Oral and gastric stages of *Gastrophilus* spp.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

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.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

4.5 Special precautions for use

Special precautions for use in animals

No special precautions are required.

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

Do not smoke or eat while handling the product.
Wash hands after use.
Do not allow cats or dogs to ingest spilled paste or access to used syringes.

4.6 Adverse reactions (frequency and seriousness)

Some horses carrying heavy infection of *Onchocerca microfilariae* have experienced oedema and pruritus following dosing, assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.

4.7 Use during pregnancy, lactation or lay

EQVALAN can be administered to mares at any stage of pregnancy or lactation. EQVALAN will not affect the fertility of breeding mares and stallions and can be given to all ages of animals including young foals.

4.8 Interaction with other medicinal products and other forms of interactions

EQVALAN Paste has been used in conjunction with other equine health care products and no interactions have been identified.

4.9 Amounts to be administered and administration route

EQVALAN Paste for Horses is given orally at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight.

Bodyweight and dosage should be accurately determined prior to treatment. For syringes intended to treat horses up to 600 kg and 1100 kg, calibrated markings are provided at 100 kg bodyweight intervals. For the syringe intended to treat horses up to 750 kg, calibrated markings are provided at 125 kg bodyweight intervals. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger.

<u>Dosing instructions</u>
Unlock the knurled ring by making ¼ turn and slide the knurled ring up the plunger shaft so that the side nearest the barrel is at the prescribed weight marking. Turn the knurled ring ¼ turn to lock in place. Remove the plastic cap from the tip of the nozzle. Make sure the horse's mouth contains no feed. Insert the syringe into the horse's mouth at the interdental space. Advance the plunger as far as it will go, depositing the medication on the base of the tongue.

<u>Parasite control program</u>
All horses should be included in a regular parasite control program, with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate.
EQVALAN Paste is highly effective against gastro-intestinal, cutaneous and pulmonary nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis and colic caused by *Strongylus vulgaris*. With its broad spectrum, EQVALAN Paste is well suited to be a major product in parasite control program and is well suited to be a major component in a rotational program.

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

Mild transitory signs (slowed pupillary light response and depression) have been seen at a dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis, ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. No antidote has been identified; however, symptomatic therapy may be beneficial.

4.11 Withdrawal period(s)

Animals intended for human consumption must not be slaughtered during treatment.Animals intended for human consumption may only be slaughtered from 21 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Anthelmintics, ivermectin.ATCvet code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind 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 parasite. 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, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic particulars

Maximum plasma concentration
The maximum plasma concentration (average of 32 ng/ml) is reached 6 hours after administration of a dose rate of 0.3mg ivermectin per kg bodyweight. This peak falls off gradually to an average level of 2 ng/ml at 10 days.

Excretion: length of time and route
Ivermectin residues (expressed as dihydro B_{1a}) in the liver, muscle, kidney, fat and blood were determined with a liquid chromatographic method with fluorescence detection. No residue (except one 28 day fat sample) reached the limit of detection of > 2 ppb 21, 28 and 42 days post dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylcellulose
Hydrogenated Castor Oil
Titanium Dioxide (E171) Propylene Glycol

6.2 Major incompatibilities

None known

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: use immediately

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

The product is available in syringes containing 6.42g, 8,03g or 11.77g of paste.
For syringe intended for the treatment of horses up to 600 kg, containing 6.42g of paste: White polypropylene syringes barrel with a white LDPE cap, a rubber rod tip and a white polypropylene plunger rod, with dose divisions calibrated by body weight with a white polypropylene stop ring.
For syringes intended for the treatment of horses up to 750 kg and 1100 kg, containing 8.03g or 11.77g of paste respectively: White polypropylene syringes barrel with a white rubber cap, a rubber rod tip and a white polypropylene plunger rod, with dose divisions calibrated by body weight with a white polypropylene stop ring.
Box of 1 syringe for oral administration of 6.42g
Box of 1 syringe for oral administration of 8.03g
Box of 1 syringe for oral administration of 11.77g
Box of 50 syringes for oral administration of 6.42g
Box of 50 syringes for oral administration of 8.03g
Box of 50 syringes for oral administration of 11.77g

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

Studies indicate that when Ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive. Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations. Do not contaminate lakes or streams as free Ivermectin may adversely affect fish and certain water-borne organisms.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/037/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

December 2021