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 substances:
Ivermectin 18.7 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Titanium dioxide (E171)	20.0 mg
Hydroxypropylcellulose	
Hydrogenated Castor Oil	
Propylene Glycol	

White, homogeneous paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Undetermined Frequeency(<1 animal / 10,000 animals treated, including isolated reports):	Oedema[1], Pruritus[1]

[1] can occur for some horses carrying heavy infection of *Onchocerca microfilariae* a few hours following treatment, 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy or lactation.

Fertility:
The veterinary medicinal product will not affect the fertility of breeding mares and stallions and can be given to all ages of animals including young foals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

The veterinary medicinal product is given orally at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight.

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

Dosing instructions
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.

Parasite control program
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.
The veterinary medicinal product 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, The veterinary medicinal product 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 21 days.
Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:
QP54AA01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Maximum plasma concentration
The maximum plasma concentration (average of 32 ng/ml) is reached 6 hours after administration of a dose rate of 0.3 mg 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 Bla) 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is available in syringes containing 6.42 g, 8,03 g or 11.77 g of

paste.
For syringe intended for the treatment of horses up to 600 kg, containing 6.42 g 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 8.03 g or 11.77 g 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 6.42 g
Box of 1 syringe for oral administration of 8.03 g
Box of 1 syringe for oral administration of 11.77 g
Box of 50 syringes for oral administration of 6.42 g
Box of 50 syringes for oral administration of 8.03 g
Box of 50 syringes for oral administration of 11.77 g
Not all pack sizes may be marketed.

5.5 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.

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as Ivermectin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/037/001

8. DATE OF FIRST AUTHORISATION

01/10/2000

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

14/11/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).