PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eqvalan Oral Paste for Horses (Ivermectin 18.7 mg/g)

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g

3. PHARMACEUTICAL FORM

Oral Paste

4. PACKAGE SIZE

6.42 grams
8.03 grams
11.77 grams

5. TARGET SPECIES

Horses

6. INDICATION(S)

The product kills the adult and larval stages of the important internal parasites of horses and donkeys. These include small redworms that are resistant to benzimidazole-based wormers, the arterial stages of the large redworm, lungworms, bots and many others.

7. DOSAGE AND ADMINISTRATION

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. Release the knurled ring by making a 1/4 turn and sliding the ring up the plunger shaft so that the side nearest the barrel is at the required weight marking. Firmly relock the ring
(the arrow heads will now be facing each other). Make sure the horse's mouth contains no feed. Remove the plastic cap from the tip of the syringe barrel and insert the syringe at the interdental space (the gap between the front and back teeth). Depress the plunger and deposit the paste over the back of the tongue. Immediately raise the horse's head for a few seconds after dosing.

8. WITHDRAWAL PERIOD

Donkeys - meat and offal: 21 days
Horses - meat and offal: 21 days
Do not use in mares producing milk for human consumption.

9. SPECIAL WARNINGS

See package leaflet for accompanying directions and user warnings.

10. EXPIRY DATE

Expiry Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light.
Do not use after the expiry date.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4177

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. FURTHER INFORMATION

Parasite control for horses, donkeys, ponies, mares and foals.
The product kills the adult and larval stages of the important internal parasites, including small redworms that are resistant to benzimidazole-based wormers, the arterial stages of large redworms, lungworms and bots, with a single dose.

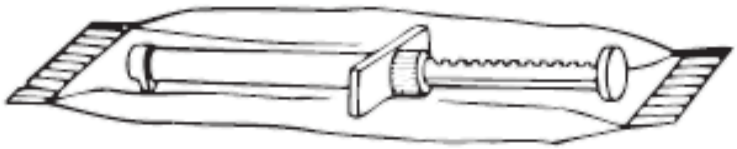
The product is a ready-to-use paste formulation containing ivermectin 18.7 mg/g.

FOR BEST RESULTS
Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations. Foals may be treated initially at 6-8 weeks of age if indicated. Collect droppings from pasture regularly.

BROAD SPECTRUM
The product kills the adult and larval stages of the important internal parasites including small redworms, the arterial stages of the large redworm, lungworms and bots with a single dose.

CONTROLS RESISTANT SMALL REDWORMS
The product kills the small redworms that are resistant to benzimidazole-based wormers.

SAFE
The product has a wide safety margin. At the recommended rate the product can be used with complete confidence in foals, mares, ponies, donkeys and horses. Mares may be treated at any stage of pregnancy and the fertility of stallions that have been dosed has not been affected.



SEALED FOR SECURITY. IF BROKEN DO NOT ACCEPT.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (SYRINGE LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eqvalan Oral Paste for Horses (Ivermectin 18.7 mg/g)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin 18.7 mg/g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6.42 grams
8.03 grams
11.77 grams

4. ROUTE(S) OF ADMINISTRATION

Oral Paste

5. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: 21 days. Do not use in mares producing milk for human consumption.

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

Expiry Date:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

9. FURTHER INFORMATION

Parasite control for horses, donkeys, ponies, mares and foals.
The product contains 18.7 mg/g ivermectin
Read package leaflet before use.
Do not store above 25°C. Protect from light.
Keep out of the sight and reach of children.

Marketing Authorisation Holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

POM-VPS

To be supplied only on veterinary prescription
Vm 08327/4177

PACKAGE LEAFLET:
Eqvalan Oral Paste for Horses (Ivermectin 18.7 mg/g)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet
31000 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eqvalan Oral Paste for Horses (Ivermectin 18.7 mg/g)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

The product is a clean, white, ready-to-use, homogenous paste formulation for oral administration containing ivermectin 18.7 mg/g and titanium dioxide (E171) 20 mg/g in disposable polypropylene syringes. Each syringe contains 6.42 g 8.03 g 11.77 g paste.

4. INDICATIONS

The product kills the adult and arterial larval stages of the important internal parasites of horses and donkeys. These include small redworms that are resistant to benzimidazole-based wormers, the arterial stages of the large redworm, lungworms, bots and many others.
The product controls the following horse parasites with one treatment

Large strongyles:
Strongylus vulgaris (adults and arterial larval stages)
Strongylus edentatus (adults and tissue larval stages)
Strongylus equinus (adults)
Triodontophorus spp. (adults): *Triodontophorus brevicauda, Triodontophorus serratus*
Craterostomum acuticaudatum (adults)
Small strongyles. Adult and immature (fourth-stage larvae) small strongyles (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
Cylicodontophorus spp.: *Cylicodontophorus bicornatus*
Cylicostephanus spp.: *Cylicostephanus asymetricus, Cylicostephanus bidentatus, Cylicostephanus calicatus, Cylicostephanus goldi, Cylicostephanus longibursatus, Cylicostephanus minutus*
Gyalocephalus capitatus
Parapoteriostomum spp.: *Parapoteriostomum euproctus, Parapoteriostomum mettami*
Petrovinema spp.: *Petrovinema poculatum*
Poteriostomum spp.: *Poteriostomum imparidentatum*

Lungworms (adult and immatures):
Dictyocaulus arnfieldi
Pinworms (adult and immatures):
Oxyuris equi
Ascarids (adult and third and fourth-stage larvae):
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 *Gasterophilus* spp.

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

Some horses have experienced reactions involving skin swellings and itching shortly after treatment. In most of these cases the horses have been diagnosed as carrying heavy infections of *Onchocerca* microfilariae and it is assumed that the reactions were the result of the death of large numbers of microfilariae. Although the signs have resolved within a few days treatment for these symptoms may be advisable. Consult your veterinary surgeon should these signs persist.

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Administer orally to horses and donkeys at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

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. Unlock the knurled ring by making a 1/4 turn and slide the ring up the plunger shaft so that the side nearest the barrel is at the required weight marking. Firmly re-lock the ring, (the arrow-heads will now be facing each other). Make sure the horse's mouth contains no feed. Remove the plastic cap from the tip of the nozzle and insert the syringe into the horse's mouth at the interdental space, (the gap between the front and back teeth). Depress the plunger as far as it will go to deposit the paste at the base of the tongue. Immediately raise the horse's head for a few seconds after dosing.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
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.

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 macrocyclic lactones (which includes ivermectin) has been reported in *Parascaris equorum* in horses in a number of countries within the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of gastro-intestinal nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

10. WITHDRAWAL PERIOD(S)

Donkeys - meat and offal: 21 days
Horses - meat and offal: 21 days
Do not use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Discard any unused material.

12. SPECIAL WARNINGS

Do not smoke, eat or drink while handling the product.
Wash hands after use. This product may cause skin and eye irritation. Therefore, the user should avoid contact of the product with the skin and the eyes. In the case of contact, rinse immediately with plenty of water.
In the case of accidental ingestion or eye irritation after contact seek medical advice immediately and show the package insert or label to the physician.

For animal treatment only.

Use during pregnancy and lactation
Mares may be treated at any stage of pregnancy and the fertility of stallions that have been dosed has not been affected.

Interaction with other medicaments and other forms of interaction
The product has been used in conjunction with other equine health care products and no interactions have been identified.

Special warnings for non-target species
The product has been formulated specifically for use in horses and donkeys only. Dogs or cats may be adversely affected by the concentration of ivermectin in this product if they are allowed to ingest spilled paste or have access to used syringes.

Overdose and safety margin
The product has a wide safety margin and can be used at the recommended dose with complete confidence in foals, mares, ponies, donkeys and horses. Mild transitory signs (slowed pupillary light response and depression) have been seen at nine times the recommended dose level (i.e. 1.8 mg/kg). Other signs seen at even higher doses include mydriasis (dilated pupils), ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. No antidote has been identified; however, symptomatic therapy may be beneficial.

Incompatibilities
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.
EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2023

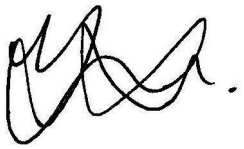
15. OTHER INFORMATION

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
Not all pack sizes may be marketed

Vm 08327/4177
To be supplied only on veterinary prescription

PARASITE CONTROL PROGRAMME

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations. Foals may be treated initially at 6-8 weeks of age if indicated. Collect droppings from pasture regularly.



Approved: 07 March 2024