PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Box containing one syringe of 7.49 g or 6.42 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aloquantel Ivermectin and Praziquantel Oral Gel For Horses

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Active Ingredients
Ivermectin 18.7 mg
Praziquantel 140.3 mg

Excipients
Titanium dioxide (E171) 20mg
Propylene glycol 731mg

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZES

Box with a syringe of 7.49 g for up to 700kg
Box with a syringe of 6.42 g for up to 600kg

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIOD.

Meat and offal: 35 days.
Not permitted for use in horses producing milk for human consumption.

9. SPECIAL WARNINGS

Read the package leaflet before use

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store opened syringes below 25°C.

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

Read the package leaflet before use.

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

[Distribution category]
For animal treatment only.
To be supplied only on veterinary prescription.

POM-VPS

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

Virbac
Premiere Avenue
2065M-L I D
F-06516 Carros Cedex
France

16. MARKETING AUTHORISATION NUMBER

Vm 05653/4175

17. MANUFACTURER'S BATCH NUMBER

Batch: number

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS – 7.49 g or 6.42 g syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aloquantel Ivermectin and Praziquantel Oral Gel For Horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each gram of the product contains: ivermectin 18.7 mg, praziquantel 140.3 mg titanium dioxide (E171) 20mg, propylene glycol 731mg.

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

7.49 g or 6.42g

4. ROUTE(S) OF ADMINISTRATION

The oral gel is administered orally by inserting the nozzle of the syringe though the interdental space and depositing the required amount of gel on the back of tongue.

5. WITHDRAWAL PERIOD

Meat and Offal : 35 days.
Not permitted for use in horses producing milk for human consumption.

6. BATCH NUMBER

Batch: number

7. EXPIRY DATE

EXP:
Once opened, use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only. Keep out of sight and reach of children.

M.A.H. :
Virbac
Premiere Avenue
2065M-L I D
F-06516 Carros Cedex
France

POM-VPS

Vm 05653/4175

Distributor : Farm & Stable, Omega House, Lakesmere Road, Hazleton Interchange, Horndean, PO8 9JU

PACKAGE LEAFLET FOR:

ALOQUANTEL IVERMECTIN AND PRAZIQUANTEL ORAL GEL FOR HORSES

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

Marketing authorisation holder:
Virbac
Premiere Avenue
2065M-L I D
F-06516 Carros Cedex
France

Manufacturer for the batch release:
Sofarimex Indústria Química e Farmacêutica Lda
Avenida das Indústrias - Alto do Colaride - Agualva – 2735-213 Cacém
Portugal

And

Virbac
1ére Avenue - 2065m - LID
06516 Carros Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aloquantel Ivermectin and Praziquantel Oral Gel For Horses

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each gram contains :
Active substances:
Active Substance:
Ivermectin 18.7 mg
Praziquantel 140.3 mg

Excipients:
Titanium dioxide (E171) 20 mg
Propylene glycol 731 mg

Almost white to cream, thick gel.

4. INDICATION(S)

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:
Cyathostomum*: 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.*

Dipteran insects: *Gasterophilus* spp. (larvae).

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

5. 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 the active substances or to any other ingredients.

6. ADVERSE REACTIONS

Horses carrying heavy infection of Onchocerca microfilariae have experienced such reactions as swelling and itching after treatment. It is assumed that these reactions are the result of the destruction of large numbers of microfilariae.

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 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.
A veterinarian should be consulted if these signs persist.

7. TARGET SPECIES

Horses

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

Posology
Single administration.
200 µg of ivermectin and 1.5 mg of praziquantel per kg of bodyweight corresponding to 1.07 g of gel per 100 kg bodyweight.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing devices should be checked as underdosing might lead to an increased risk of development of resistance to anthelmintic drugs.

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	601-650 kg	6.955 g
301-350 kg	3.745 g	651-700 kg	7.490 g
351-400 kg	4.280 g		

The first division delivers enough gel to treat 100 kg.
Each subsequent syringe division delivers enough gel to treat 50 kg of bodyweight.

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 gel delivers sufficient paste to treat 600 kg of bodyweight at the recommended dose rate.
The syringe containing 7.49 g of gel delivers sufficient gel to treat 700 kg of bodyweight at the recommended dose rate.

9. ADVICE ON CORRECT ADMINISTRATION

Oral use
Before administration, adjust the syringe to the calculated dosage by setting the ring on the plunger. The gel is administered orally by inserting the nozzle of the syringe through the interdental space and depositing the required amount of gel 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.

10. WITHDRAWAL PERIOD(S)

Meat and offal : 35 days. Do not use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C. Store opened syringes below 25°C
Store in the original packaging.
Do not use after the expiry date which is stated on the label and carton after EXP.
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the syringe: 6 months.
When the syringe is used for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the syringe should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species
The product can be used safely in stallions.
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 (an avermectin) has been reported in Parascaris equorum in horses in a number of countries including the EU. Therefore the use of this product 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.

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 gel or access to used syringes due to the potential for adverse effects related to ivermectin toxicity.
Parasite resistance to a particular class of anthelmintic 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 this product.
In the event of accidental ingestion, seek medical advice and show the package leaflet to the doctor.

Use during pregnancy, lactation or lay
The product can be used safely in mares during the whole pregnancy period and lactation period.

Interaction
The effects of GABA agonists ae increased by ivermectin.

Overdose
A tolerance study performed in foals from 2 weeks of age with doses up to 5 times the recommended dosage showed no adverse reactions.
Safety studies conducted with the veterinary medicinal product administered to mares at 3 times the recommended dosage at 14-day intervals during the whole gestation and lactation did not show any abortions, any adverse effects on the gestation, parturition and on the mare general health, nor any abnormalities on the foals.
Safety studies conducted with the veterinary medicinal product administered to stallions at 3 times the recommended dosage did not show any adverse effects, in particular on the reproductive performances.

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

Any unused product or waste material should be disposed of in accordance with national requirements. EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface water or ditches with the product or used containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2021

15. OTHER INFORMATION

The product is presented in 7.49 g or 6.42 g plastic syringes made from polyethylene and graduated in 100 kg body weight graduations.
Product presentations:
Box of 1, 12, or 48 syringes.
Blister of one syringe.
Not all pack sizes may be marketed.

POM-VPS For animal treatment only.

To be supplied only on veterinary prescription
Vm 05653/4175 UK authorised veterinary medicinal product
Distributor : Farm & Stable, Omega House, Lakesmere Road, Hazleton Interchange, Horndean, PO8 9JU

Approved: 11/01/21