ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BLISTER OF 1 SYRINGE
BOX CONTAINING 1, 2, 12, 40 OR 48 SYRINGE(S)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax oral gel

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:18.7 mg ivermectin and 140.3 mg praziquantel

3. PACKAGE SIZE

1 syringe of 6.42 g.
2 syringes of 6.42 g
12 syringes of 6.42 g
40 syringes of 6.42 g
48 syringes of 6.42 g

1 syringe of 7.49 g
2 syringes of 7.49 g
12 syringes of 7.49 g
40 syringes of 7.49 g
48 syringes of 7.49 g

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

Vm 05653/3012

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

6.42 g
7.49 g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equimax oral gel for horses

2. Composition

Each gram contains

Active substances:
Ivermectin ..... 18.7 mg
Praziquantel…….. 140.3 mg

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

Almost white to creamy, thick, unctuous and smooth paste.

3. Target species

Horses.

4. Indications for use

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 cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:

Care should be taken to avoid the following practices because they increase the risk of the 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 veterinary medicinal 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 veterinary medicinal 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.

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 can not 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 veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:
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 paste or access to used syringes due to the potential for adverse effects related to ivermectin toxicity.

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

Fertility:
The veterinary medicinal product can be used safely in stallions.

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 mares 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.

7. Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Colic [1, 3,] Loose Stool [2], Diarrhoea [3] Anorexia (Not eating)[3] Allergic reaction (such as hypersalivation (increased salivation), lingual oedema (swelling of the tongue), urticaria (hives), tachycardia (rapid heart rate), congested mucous membrane, allergic oedema (swelling))
Undetermined frequency (cannot be estimated from the available data)
Swelling [4] Itching [4]

[1] Mild transient in case of very high levels of infestation, caused by destruction of the parasites
[2] In case of very high levels of infestation, caused by destruction of the parasites
[3] In particular when there is heavy worm burden.
[4] For horses carrying heavy infection of Onchocerca microfilariae. It is assumed that these reactions are the result of the destruction of large numbers of microfilariae.

A veterinarian should be consulted if these signs persist.

Reporting adverse events is important. It allows continuous safety monitoring of a product.If you notice any side effects, even those not already listed in in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use.

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		

* Concerns the 7.49g syringe only

9. Advice on correct administration

Posology:
Single administration.
200 µg of Ivermectin and 1.5 mg of praziquantel per kg of bodyweight corresponding to 1.07 g of paste per 100 kg bodyweight.

To ensure a correct dosage, body weight should be determined as accurately as possible, accuracy of the dosing device should be checked as underdosing might lead to an increased risk of development of resistance to anthelmintic drugs.
The first division delivers enough paste to treat 100 kg.
Each subsequent syringe division delivers enough paste 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 paste delivers sufficient paste to treat 600 kg of bodyweight at the recommended dose rate.
The syringe containing 7.49 g of paste delivers sufficient paste to treat 700 kg of bodyweight at the recommended dose rate.

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

Meat and offal: 35 days.
Not authorised for use in horses 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.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton. The expiry date refers to the last day of the month.

Shelf life after first opening the immediate packaging: 6 months

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous to 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 05653/3012

Box of 1, 2, 12, 40 or 48 syringes.
Blister of one syringe.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Manufacturer responsible for batch release:
SOFARIMEX Industria Quimica e Farmaceutica Ltd
Avenida das Industrias Alto de Lolaride
Agualva – 2735 Cacem
Portugal

OR

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 04 May 2024