ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX CONTAINING 1 BLISTER OF 1 SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax oral gel for horses.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substances : ivermectin, praziquantel.
1 g of gel contains 18.7 mg ivermectin and 140.3 mg praziquantel
Exipients : Titanium dioxide (E171), propylene glycol

3. PHARMACEUTICAL FORM

Oral gel.

4. PACKAGE SIZE

1 blister of 1 syringe of 6,42 g.

5. TARGET SPECIES

Horses.

6. INDICATION(S)

Treatment of mixed cestode and nematode or arthropod infestations, due to adult and immature roundworms, lungworms, bots and tapeworms in horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
Shelf-fife after first opening of the container : 6 months.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store opened syringes below 25°C.
Shelf-life after first opening of the container : 6 months.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 waters or ditches with the product or used container.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

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

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC DE PORTUGAL - LABORATÓRIOS, LDA
Rua do Centro Empresarial
Edifício 13, Escritório 3, Piso 1
Quinta da Beloura
P 2710 693 Sintra
PORTUGAL

16. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER OF 1 SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax oral gel for horses.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin	18.7	mg
Praziquantel.....	140.3	mg

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

1 syringe of 6,42 g.
1 syringe of 7,49 g.

4. ROUTE(S) OF ADMINISTRATION

Oral route.

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Equimax 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 DE PORTUGAL - LABORATÓRIOS, LDA
Rua do Centro Empresarial
Edifício 13, Escritório 3, Piso 1
Quinta da Beloura
P 2710 693 Sintra
PORTUGAL

Manufacturer for the batch release:

SOFARIMEX Industria Quimica e Farmaceutica Ltd
Avenida das Industrias Alto de Lolaride – Agualva – 2735 Cacem
Portugal

OR

VIRBAC
1ère avenue – 2065 m – L.I.D. – 06516 Carros - France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimax oral gel for horses.

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

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

Active substances :
Ivermectin ..... 18,7 mg
Praziquantel…….. 140,3 mg

Other ingredients : titanium dioxide (E171), propylene glycol

1 g of gel contains 18.7 mg ivermectin and 140.3 mg paraziquantel

4. INDICATION(S)

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 active ingredients 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, diarrhea 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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

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.

Bodyweight and dosage should be accurately determined prior to treatment 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
Oral 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 PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C. Store opened syringes below 25°C.
Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton. Shelf-life after first opening of the container : 6 months

12. SPECIAL WARNING(S)

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 product.
In the event of accidental ingestion, seek medical advice and show the doctor the leaflet so that he knows what you have taken.

Special warnings for each target species

The product can be used safely in stallions.

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 paste 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.

Use during pregnancy, lactation or lay

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

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 waters or ditches with the product or used container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED