ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box or blister containing one 6.42 g or 7.49 g syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAQUELL 18.7 mg/g Oral Paste

Ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin ..... 18.7 mg/g.
Titanium dioxide

3. PHARMACEUTICAL FORM

Oral paste.

4. PACKAGE SIZE

Box of 1 syringe of 6.42 g/7.49 g
Box of 2 syringes of 6.42 g/7.49 g
Box of 12 syringes of 6.42 g/7.49 g
Box of 40 syringes of 6.42 g/7.49 g
Box of 48 syringes of 6.42 g/7.49 g
Blister of 1 syringe of 6.42 g/7.49 g

5. TARGET SPECIES

Horses.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal : 30 days.
Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 6 months.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in the original packaging.

12. SPECIAL 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

For animal treatment only.

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 S.A.
1ère avenue, 2065m - LID
06516 Carros
Cedex
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4202

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAQUELL 18.7 mg/g Oral Paste
Ivermectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

18.7 mg/g

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

6.42 g
7.49 g

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD

Read the package leaflet before use.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use within 6 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

ERAQUELL 18.7 mg/g Oral Paste

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 S.A.
1ère avenue, 2065m - LID
06516 Carros
Cedex
France

Manufactures for the batch release:
Virbac
1ère avenue -2065m – L.I.D.
06516 Carros
France

Sofarimex Indústria Química e Farmacêutica Ltd
Avenida das Indústrias
Alto de Colaride
Agualva 2735-213
Cacém
Portugal

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAQUELL 18.7 mg/g Oral Paste
Ivermectin

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

Active substances:
Active Substance:
Ivermectin ..... 18.7 mg/g.

Excipients:
Titanium dioxide (E171).

White and thick paste.

4. INDICATION(S)

Roundworms in the stomach and intestines.

Large strongyles:
Strongylus vulgaris: adults and 4th larval (arterial) stages

Strongylus edentatus: adults and 4th larval (tissue) stages
Strongylus equinus: adults

Small strongyles, adults:
Cyathostomum spp.
Cylicocyclus spp.
Cylicodontophorus spp.
Cylicostephanus spp.
Gyalocephalus spp.

Hairworms:
Trichostrongylus axei: adults

Pinworms:
Oxyuris equi: adults and immatures

Ascarids:
Parascaris equorum: adults

Intestinal threadworms:
Strongyloides westeri: adults

Large-mouth stomach worms:
Habronema muscae: adults

Neck threadworms:
Onchocerca spp. (microfilariae)

Lungworms:
Dictyocaulus arnfieldi: adult and immature

Stomach bots:
Gasterophilus spp.: oral and gastric larval stages

5. CONTRAINDICATIONS

Do not use in dogs or cats as severe adverse reactions may occur.
Do not use in cases of known hypersensitivity to the active substance.
See also the section ”Withdrawal period”.

6. ADVERSE REACTIONS

Some horses carrying heavy infection of Onchocerca microfilariae have experienced reactions with swelling and itching following dosing, 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.

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

A single administration of 200 µg ivermectin per kg of bodyweight.

Each syringe division mark plunger delivers enough paste to treat 100 kg of bodyweight (which corresponds to 1.07 g of product and 20 mg of ivermectin).

The syringe containing 6.42 g of paste delivers sufficient paste to treat 600 kg of bodyweight at the recommended dose range.

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

9. ADVICE ON CORRECT ADMINISTRATION

Horse weight should be accurately determined for the correct use of the paste. The animal's mouth should be free of food. The syringe must be positioned between the front and back teeth and the paste must be placed on the base of the horse’s tongue. Immediately elevate the head of the horse for a few seconds to ensure deglutition.
Re-treatment should be done according to the epidemiological situation, but not at less than 30 days interval.

10. WITHDRAWAL PERIOD

Meat and offal : 30 days.
Do not use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 30°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 after first opening the syringe: 6 months.

12. SPECIAL WARNING(S)

Special warnings for each target species
Strategies that should be avoided because they might lead to an increased risk of development of resistance to anthelmintic drugs include:

• 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. 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 has been reported in Parascaris equorum in horses. 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 with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).
As ivermectin is extremely dangerous to fish and aquatic life treated animals should not have direct access to surface water and ditches during treatment.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.
As with all anthelmintics, a veterinary surgeon should establish appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not eat, drink or smoke while handling the product. Avoid contact with skin and eyes. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and, if necessary, get medical attention.
Wash hands after use.

Use during pregnancy, lactation or lay
Can be used in pregnant mares.

Interaction
The effects of GABA agonists are increased by ivermectin.

Overdose
Mild transitory signs (slowed pupillary light response and depression) have been seen at a higher 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. Although no antidote has been identified, symptomatic therapy may be beneficial.

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

Ivermectin is extremely dangerous to fish and aquatic life. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Do not contaminate surface water or ditches with the product or used containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

The product is presented in 6.42 g or 7.49 g plastic syringes made from polyethylene and graduated in 100 kg body weight graduations.

Product presentations:

6.42 g syringe:
Box of 1, 2, 12, 40 or 48 syringes.
Blister of 1 syringe.

7.49 g syringe:
Box of 1, 2, 12, 40 or 48 syringes.
Blister of 1 syringe.

Not all pack sizes may be marketed.

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.