ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAQUELL 18.7 mg/g Oral Paste (AT, BE, DE, EL, FI, FR, IT, IR, LU, NL, UK)
ERAQUELL vet. 18.7 mg/g Oral Paste (NO, SE)
EQUIMEL 18.7 mg/g Oral Paste (ES, PT)
VIRBALAN vet. 18.7 mg/g Oral Paste (DK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:
Active Substance:
Ivermectin ..... 18.7 mg.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Titanium dioxide (E171)	0.02 g
Hydrogenated castor oil	
Hydroxypropylcellulose	
Propylene glycol	

White and thick paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

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

3.3 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 or to any of the excipients.

See also section 3.12 “Withdrawal periods”.

3.4 Special warnings

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 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Special precautions for the protection of the environment:
As ivermectin is extremely dangerous to fish and aquatic life treated animals should not have direct access to surface water and ditches during treatment.

Other precautions:
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).

3.6 Adverse events

Horses:

Undetermined Frequency (cannot be estimated from the available data)	Swelling* Itching*

*For some horses carrying heavy infection of *Onchocerca* microfilariae and 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used in pregnant mares.
See also section 3.12 “Withdrawal periods”.

3.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by ivermectin.

3.9 Administration routes and dosage

Oral use.

Posology:
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 veterinary medicinal 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.

Directions for use:
To ensure a correct dosage, body weight should be determined as accurately as possible. 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal : 30 days.
Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP 54 AA 01

4.2 Pharmacodynamics

Ivermectin is a macrocyclic lactone derivative and acts by inhibiting nerve impulses. It binds selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the relevant parasites. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA). The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels. The macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

4.3 Pharmacokinetics

After oral administration of the recommended doses to horses, the following parameters were observed: Cmax of 48.79 ng/ml, Tmax of 5.5 hours, elimination half-life of 61 hours. Ivermectin is eliminated primarily via the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening of the immediate packaging: 6 months.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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

Pack sizes:

6.42 g syringe:
Box of 1, 2, 12, 40 or 48 syringes.
Transparent PVC blister sealed onto a carton sheet containing one syringe

7.49 g syringe:
Box of 1, 2, 12, 40 or 48 syringes.
Transparent PVC blister sealed onto a carton sheet containing one syringe

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste material derived thereof of in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Do not contaminate surface water or ditches with the veterinary medicinal product or used containers.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

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 (AT, BE, DE, EL, FI, FR, IT, IR, LU, NL, UK)
ERAQUELL vet. 18.7 mg/g Oral Paste (NO, SE)
EQUIMEL 18.7 mg/g Oral Paste (ES, PT)
VIRBALAN vet. 18.7 mg/g Oral Paste (DK)

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g.

3. PACKAGE SIZE

1 syringe of 6.42 g
1 syringe of 7.49 g
2 syringes of 6.42 g
2 syringes of 7.49 g
12 syringes of 6.42 g
12 syringes of 7.49 g
40 syringes of 6.42 g
40 syringes of 7.49 g
48 syringes of 6.42 g
48 syringes of 7.49 g
1 syringe of 6.42 g
1 syringe of 7.49 g

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal : 30 days.
Not authorised for use in mares 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 in the original package.

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

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ERAQUELL (AT, BE, DE, EL, FI, FR, IT, IR, LU, NL, UK)
ERAQUELL vet. (NO, SE)
EQUIMEL (ES, PT)
VIRBALAN vet. (DK)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

18.7 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ERAQUELL 18.7 mg/g Oral Paste (AT, BE, DE, EL, FI, FR, IT, IR, LU, NL, UK)
ERAQUELL vet. 18.7 mg/g Oral Paste (NO, SE)
EQUIMEL 18.7 mg/g Oral Paste (ES, PT)
VIRBALAN vet. 18.7 mg/g Oral Paste (DK)

2. Composition

Each gram contains:
Active substance:
Ivermectin ..... 18.7 mg.
Excipients:
Titanium dioxide (E171) ..... 0.02 g.

White and thick paste.

3. Target species

Horses.

4. Indications for use

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 periods".

6. Special warnings

Special warnings:
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 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.

Special precautions for safe use in the target species:
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.

Special precautions for the protection of the environment:
As ivermectin is extremely dangerous to fish and aquatic life treated animals should not have direct access to surface water and ditches during treatment.

Other precautions:
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).

Pregnancy:
Can be used in pregnant mares.
See also section "Withdrawal periods".

Interaction with other medicinal products and other forms of 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

7. Adverse events

Horses:

Undetermined frequency (cannot be estimated from the available data)
Swelling*, Itching*

*For some horses carrying heavy infection of *Onchocerca* microfilariae and 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.

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 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.

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

To ensure a correct dosage, body weight should be determined as accurately as possible. 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 periods

Meat and offal : 30 days.
Not authorised for 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 in the original package.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that 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 for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste material derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Do not contaminate surface water or ditches with the veterinary medicinal product or used containers.

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

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

Pack sizes:

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 veterinary medicinal 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.

15. Date on which the package leaflet was last revised

{MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

VIRBAC
1ère avenue 2065 m LID
06516 Carros
France
<telephone number>

Manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

or:

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

Local representatives and contact details to report suspected adverse reactions: