ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec 10 mg/ml solution for injection for swine (ES FR)
Virbamec-S 10 mg/ml solution for injection for swine (DE LU)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injection contains:

Active substance:
Ivermectin 10 mg

Excipient:

Qualitative composition of excipients and other constituents
Glycerol formal

Clear, slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Swine.

3.2 Indications for use for each target species

For the treatment of:

Gastro-intestinal roundworms (adult and fourth-stage larvae):
Ascaris suum (adult and L4)
Hyostrongylus rubidus (adult and L4)
Oesophagostomum spp. (adult and L4)
Strongyloides ransomi (adult)

Lungworms
Metastrongylus spp. (adult)

Sucking lices
Haematopinus suis

Mange mites
Sarcoptes scabiei var. suis

3.3 Contraindications

Do not use by the intramuscular or intravenous route.
Do not use in cases of hypersensitivity to the active substance.
See also section 3.7.

3.4 Special warnings

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 veterinary medicinal product, or lack of calibration of the dosing device.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Frequent and repeated use may lead to the development of resistance. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid underdosing, animals should be grouped according to their body weight and dosed according to the heaviest animal in the group.

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.

Avoid the introduction of contamination during use.
Should any apparent growth or discolouration occur, the veterinary medicinal product should be discarded.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not smoke or eat during the administration.
Wash hands carefully after use.
Dermal irritation or irritation of eyes are possible. Avoid direct dermal contact with the product. Should the veterinary medicinal product inadvertently get into the eyes, wash with water and seek medical advice.
Take care to avoid self-administration, as the product may cause local irritation and/or pain at the site of injection.

Special precautions for the protection of the environment:

Not applicable.

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 and crosses, and also in turtles/tortoises).

3.6 Adverse events

Swine :

Rare (1 to 10 animals / 10,000 animals treated):	Disorders of general condition[1]
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Pain[1]
Undetermined frequency (cannot be estimated from the available data):	Injection site swelling[1, 2]

[1]Transient.
[2]Disappears without treatment.

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

The veterinary medicinal product should not be used in sows in the first term of the pregnancy (1-40 days).

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use.

1.5 ml of the veterinary medicinal product per 50 kg body weight, equivalent to 0.3 mg ivermectin per kg bodyweight.

Single subcutaneous injection, preferably under the loose skin, at the base of the ear.
Treatment may be repeated at intervals of not less than 21 days.
For single administration only.
To ensure a correct dosage, body weight should be determined as accurately as possible.

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

After administering an overdose, symptoms like tremor, convulsions and coma have been observed. These cases should be treated symptomatically.

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: 35 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

Ivermectin is a highly active, broad spectrum, internal and external antiparasitic of the avermectine family.
Ivermectin is obtained by chemical modification of avermectin B1a fermentation production of the actinomycete *Streptomyces avermitilis*.
Ivermectin acts by inhibiting nerve impulses.
Its mode of action includes γ-aminobutyric acid (GABA), neurotransmitter inhibitor at the level of presynaptic nerve terminations or at the level of neuromuscular junctions. Ivermectin stimulates GABA liberation at presynaptic nerve terminations (in Nematodes) or the neuromuscular junctions (in Arthropodes like ticks, flies and fleas), which leads to the paralysis and death of the relevant parasites.
Avermectines are generally well tolerated in mammals, due to lack of glutamate-receptors in chloride-ion-channels and very low affinity of macrocyclic lactones to GABA-dependent receptors.

4.3 Pharmacokinetics

The biological half-life afforded by an injectable formulation of ivermectin is significantly longer than the intrinsic half-life of the drug (intravenous bolus). Slower absorption associated with the parenteral route (subcutaneous injection), compared to the oral administration, has been attributed to precipitation of the drug at the injection site.

The low solubility of ivermectin in water, its formulation in non-aqueous preparation and its deposition in the subcutaneous tissue favour a slow absorption from the site of injection, which may account for its prolonged residence in the bloodstream.

Following a subcutaneous administration of the recommended dosage (1 ml per 33 kg body weight), the ivermectin plasma peak is observed after 2.75 days with 13.71 ng/ml and the elimination half-life is 2.75 days.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Size: 200 ml, 500 ml.
Container: colourless low density polyethylene vial.
Closure: rubber bung with aluminium overseal and plastic overcap.

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 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

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 with 1 vial of 200 or 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec 10 mg/ml solution for injection (ES FR)
Virbamec-S 10 mg/ml solution for injection (DE LU)

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 10 mg/ml

3. PACKAGE SIZE

200 ml
500 ml

4. TARGET SPECIES

Swine

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Meat and offal: 35 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

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}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

200 ml or 500 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec 10 mg/ml solution for injection (ES FR)
Virbamec-S 10 mg/ml solution for injection (DE LU)

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 10 mg/ml

3. TARGET SPECIES

Swine

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 35 days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.
Once opened, use by……

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Virbamec 10 mg/ml solution for injection for swine (ES FR)
Virbamec-S 10 mg/ml solution for injection for swine (DE LU)

2. Composition

Active substance:
Ivermectin 10 mg/ml

Clear, slightly yellow solution.

3. Target species

Swine.

4. Indications for use

For the treatment of:

Gastro-intestinal roundworms (adult and fourth-stage larvae) :
Ascaris suum (adult and L4)
Hyostrongylus rubidus (adult and L4)
Oesophagostomum spp. (adult and L4)
Strongyloides ransomi (adult)

Lungworms
Metastrongylus spp. (adult)

Sucking lices
Haematopinus suis

Mange mites
Sarcoptes scabiei var. suis

5. Contraindications

Do not use by the intramuscular or intravenous route.
Do not use in cases of hypersensitivity to the active substance.
See also section "Special warnings, pregnancy".

6. Special warnings

Special warnings:

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 usse 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.

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.

Special precautions for safe use in the target species:

Frequent and repeated use may lead to the development of resistance. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid underdosing, animals should be grouped according to their bodyweight and dosed according to the heaviest animal in the group.

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.

Avoid the introduction of contamination during use.
Should any apparent growth or discolouration occur, the veterinary medicinal product should be discarded.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not smoke or eat during the administration.
Wash hands carefully after use.
Dermal irritation or irritation of eyes are possible. Avoid direct dermal contact with the product. Should the veterinary medicinal product inadvertently get into the eyes, wash with water and seek medical advice.
Take care to avoid self-administration, as the product may cause local irritation and/or pain at the site of injection.

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 and crosses, and also in turtles/tortoises).

Pregnancy:

The veterinary medicinal product should not be used in sows in the first term of the pregnancy (1-40 day).

Overdose:

After administering an overdose, symptoms like tremor, convulsions and coma have been observed.
These cases should be treated symptomatically.

7. Adverse events

Swine:

Rare (1 to 10 animals / 10,000 animals treated):
Disorders of general condition[1]
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):
Pain[1]
Undetermined frequency (cannot be estimated from the available data):
Injection site swelling[1, 2]

[1]Transient.
[2] Disappears without treatment.

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

Subcutaneous use.

1.5 ml of the veterinary medicinal product per 50 kg body weight, equivalent to 0.3 mg ivermectin per kg bodyweight.

9. Advice on correct administration

Single subcutaneous injection, preferably under the loose skin, at the base of the ear.
Treatment may be repeated at intervals of not less than 21 days.
For single administration only.
To ensure a correct dosage, body weight should be determined as accurately as possible.

10. Withdrawal periods

Meat and offal: 35 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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

This 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 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

Pack sizes:
200 ml, 500 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Or

SOFARIMEX Industria Quimica e Farmaceutica Lda
Avenida das Industrias Alto de Colaride
Agualva – 2735 Cacem
Portugal

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.