ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC 10 mg/ml injectable solution for swine
solution for injection
for swine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injection contains:

Active substance:

Ivermectin 10.00 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
White or yellowish-white, crystalline powder.

4. CLINICAL PARTICULARS

4.1 Target species

Swine.

4.2 Indications for use, specifying the 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

4.3 Contraindications

Do not use by the intramuscular or intravenous route.
Do not use in case of known hypersensitivity to the active ingredient.
See also section 4.7.

4.4 Special warnings for each target species

Care should be taken to avoid the following practices because they increase the risk of development of resistence 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 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.

4.5 Special precautions for use

Special precautions for use in animals

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

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).

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 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 product inadvertantly get into the eyes, wash with water and seek medical advice.
Take care to avoid self administration, the product may cause local irritation and/or pain at the site of injection.

4.6 Adverse reactions (frequency and seriousness)

Isolated transient swellings at the injection site have been observed. This reaction disappears without treatment.
Transient pain has been observed in very rare cases.
In rare cases transient disorders of general condition have been observed.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For single administration only.
Bodyweight and dosage should be accurately determined prior to treatment to avoid underdosing.

1,5 ml VIRBAMEC injectable solution for swine 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Swine : Meat and offal: 35 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: endectocide (macrocyclic lactone)
ATCvet code: QP54AA01

5.1 Pharmacodynamic properties

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-dependend receptors.

5.2 Pharmacokinetic particulars

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 bodyweight), the ivermectin plasma peak is observed after 2.75 days with 13.71 ng/ml and the elimination half-life is 2.75 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal

6.2 Incompatibilities

None known.

6.3 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.

6.4. Special precautions for storage

Store in the orignal package and protect from light.

6.5 Nature and composition of immediate packaging

Size : 50, 200 and 500 ml.
Container : Colourless low density polyethylene vial
Closure : Rubber bung with aluminium overseal and plastic overcap

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

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

7. MARKETING AUTHORISATION HOLDER

VIRBAC de Portugal Laboratórios Lda
Rua de Centro Empresarial
Edifício 13, Escritório 3, Piso 1
Quinta da Beloura
P 2710 693 Sintra
PORTUGAL

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

Prohibition of sale, supply and/or use
Not applicable.