Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec Injectable Solution for Cattle, Swine and Sheep 10 mg/ml.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ivermectin	10	mg

Excipients:

Glycerol formal to	1	ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

A ready-to-use, sterile, non-aqueous solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, swine and sheep.

4.2 Indications for use, specifying the target species

Virbamec Injectable Solution for Cattle, Swine and Sheep is indicated for the treatment and control of the following species of gastro-intestinal roundworms, lungworms, eyeworms, warbles, mites and lice.

In cattle

Gastro- intestinal roundworms (adult and fourth-stage larvae):

Ostertagia spp (including inhibiting *O. ostertagi*)
Ostertagia lyrata
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia spp.
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
Nematodirus spathiger (adult)
Toxocara vitulorum (adult)
Trichuris spp. (adult)

Lungworms (adult and fourth- stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp

Warbles:
Hypoderma bovis
Hypoderma lineatum

Mange Mites**:**
Psoroptes bovis
Sarcoptes scabiei var bovis

Sucking Lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

Vibamec Injectable solution for Cattle, Swine and Sheep may also be used as an aid in the control of the biting louse *Damalinia bovis* and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Persistent activity

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with Virbamec Injectable Solution for Cattle, Swine and Sheep at the recommended dose rate controls re-infection with *Cooperia* spp. for at least 7 days after treatment, *Haemonchus placei* acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of Virbamec Injectable Solution for Cattle, Swine and Sheep it is recommended that calves which are set-stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season provided they are set-stocked, all the calves are included in the programme and that no untreated cattle are added to the pasture. Treated animals should always be monitored according to good husbandry practices.

In Sheep

Virbamec Injectable Solution for Cattle, Swine and Sheep is indicated for the treatment and control of psoroptic mange (sheep scab), gastro-intestinal nematodes, lungworms and nasal bots of sheep.

Gastro-intestinal roundworms (adult and fourth stage larvae)

Ostertagia circumcincta (including inhibited *O. circumcinta*)
O. trifurcata
Haemonchus contortus (including inhibited *H. contortus*)
Trichostongylus axei (adult)
Trichostrongylus colubriformis (adult)
Trichostongylus vitrinus (adult)
Cooperia curticei
Oesophagostomum venulosum (adult)
Oesophagostomum columbanium
Nematodirus filicollis
Chabertia ovina
Trichuris ovis (adult)

Lungworms (adult and fourth-stage larvae):

Dictyocaulus filaria
Protostrongylus rufescens (adult)

Mange mites*:

Psoroptes ovis

Nasal bots (all larvae stages):

Oestrus ovis

Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia circumcinta* are also controlled.

*For the treatment and control of sheep scab, 2 injections with a seven-day interval are required to treat clinical signs of scab to eliminate mites.

In Swine

Virbamec Injectable Solution for Cattle, Swine and Sheep is indicated for the treatment and control of gastro-intestinal nematodes, lungworms, lice and mange mites of pigs.

Gastro-intestinal roundworms (adult and fourth stage larvae):

Ascaris suum
Hyostongylus rubidus
Oesophagostomum spp
*Stongyloides ransomi** (adult)

Lungworms:

Metastongylus spp (adult)

Lice:

Haematopinus suis

Mange Mites:

Sarcoptes scabiei var. suis

* includes somatic larval stages

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.
Do not administer by the intravenous or intramuscular route.

4.4 Special warnings for each target species

Treatment of psoroptic mange (sheep scab) with one injection is not recommended, because, although a clinical improvement may be seen, elimination of all mites may not occur.
Sheep scab is an extremely contagious external parasite of sheep. Following treatment of infected sheep great care must be taken to avoid re-infestation, as mites may be viable for up to 15 days off the sheep. It is important to ensure that all sheep which have been in contact with infected sheep are treated. Contact between treated, infected and non-treated, non-infected flocks must be avoided until at least 7 days after the last treatment.

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 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.

Certain cases of resistance to ivermectin has been reported in *Ostertagia ostertagi* in cattle. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals

When using the 200 ml and 500 ml pack sizes, use only automatic syringe equipment.

Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal results are reported in dogs – especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Do not smoke or eat whilst handling the product.
Wash hands after use.
Take care to avoid self-administration: the product may cause irritation and/ or pain at the site of injection.

4.6 Adverse reactions (frequency and seriousness)

Cattle
A low incidence of soft-tissue swelling at the injection site has been observed. These reactions have disappeared without treatment.

Sheep
Discomfort, sometimes intense but usually transient has been observed in some animals immediately following subcutaneous administration.
Local reaction at the injection site (characterised by swelling and thickening of the skin) has been observed in treated animals. Typically, these reactions are transient.

4.7 Use during pregnancy, lactation or lay

The product can be administered during pregnancy (for information on use in lactating animals, see section 4.11).
The fertility of males is not affected by administration of the product.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Virbamec Injectable Solution for Cattle, Swine and Sheep should be given only by subcutaneous injection at the recommended dosage level of 2 mg ivermectin per 10 kilogram bodyweight for cattle and sheep and 3 mg ivermectin per 10 kg bodyweight for pigs. Each ml contains 10 mg of ivermectin. Inject under the loose skin in front of or behind the shoulders, using aseptic precautions. The injection may be given with any standard automatic multidose or single dose hypodermic syringe. A sterile 17 gauge ½ inch needle is recommended.

Cattle: 1 ml per 50 kg bodyweight

Swine: 1 ml per 33 kg bodyweight
For young pigs, especially those below 16 kg for which less than 0.5 ml is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver as little as 0.1ml is recommended.

Sheep: 0.5 ml per 25 kg bodyweight.
For young lambs weighing less than 20.0 kg give 0.1 ml per 5 kg. In these lambs the use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

For the treatment and control of Psoroptes ovis (sheep scab), two injections with a seven-day interval are required to treat clinical signs of scab and to eliminate living mites. Repeat treatments should be administered at different sites.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Use properly calibrated dosing equipment.

The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control.

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

Clinical symptoms of ivermectin toxicity include ataxia and depression. No antidote has been identified. In case of overdose, symptomatic treatment should be given.

4.11 Withdrawal Period(s)

Meat and offal:
Cattle: 49 days
Sheep: 42 days
Swine: 35 days

Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers, within 60 days of calving.
Do not use in lactating ewes producing milk for human consumption. Do not use in sheep, which are intended to produce milk for human consumption, within 60 days of lambing.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, ivermectin.
ATCvet code: QP54AA01.

5.1 Pharmacodynamic properties

Ivermectin is a highly active, broad spectrum, internal and external antiparasitic of the avermectin family. Ivermectins are isolated after fermentation of the soil organism *Streptomyces avermitilis*. 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.

5.2 Pharmacokinetic properties

Following the subcutaneous administration of 200 μg ivermectin/kg to cattle, a mean maximum plasma concentration of 54 ng/ml was detected at approximately 54 hours after treatment. The mean elimination half-life was approximately 5 days.
Following the subcutaneous administration of 200 μg ivermectin/kg to sheep, a mean maximum plasma concentration of 31 ng/ml was detected at approximately 36 hours after treatment. The mean elimination half-life was approximately 1.75 days.
Following the subcutaneous administration of 300 μg ivermectin/kg to pigs, a mean maximum plasma concentration of 14 ng/ml was detected at approximately 36 hours after treatment. The mean elimination half-life was approximately 2.75 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal

6.2 Incompatibilities

In the absence of compatability studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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: 3 months.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and composition of immediate packaging

Supplied in 50 ml, 200 ml, 500 ml and 1000 ml colourless LDPE plastic flasks sealed with a rubber “Type I” bung secured by an aluminium seal.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Ivermectin is EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.Treated animals should not have direct access to surface water of ditches. Do not contaminate surface water of ditches with the product or used container.

7 MARKETING AUTHORISATION HOLDER

Virbac
1 ére avenue - 2065 m - LID
06516 Carros
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/107/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal of the last authorisation: 20th January 2010

10 DATE OF REVISION OF THE TEXT

April 2016