1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAMEC injectable solution 10 mg/ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance
Ivermectin 10.0 mg

Excipients
Glycerol formal to 1 ml
For a full list of excipients, see 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

Virbamec Injectable Solution is indicated for 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 inhibited *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 scabei var.bovis

Sucking Lice: *Linognathus vituli Haematopinus eurysternus Solenopotes capillatus*

Virbamec Injectable Solution 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.

In Cattle
Persistent Activity:

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with Virbamec Injectable Solution 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 *Dyctiocaulus viviparus* acquired up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of Virbamec Injectable Solution for cattle 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.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active ingredient.

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 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. 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

Do not use by the intravenous or intramuscular route.

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. 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 under-dosing, animals should be grouped according to their bodyweight and dosed according to the dose of the heaviest animal in the group.

Special precautions to be taken by the person administering the veterinary 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)

Studies have shown a wide safety margin, at the recommended dosage, no adverse effect on breeding performance were observed.

At therapeutic doses, Ivermectin has no adverse effect on cattle since it does not readily penetrate their central nervous systems.

Transitory discomfort has been observed in some cattle following subcutaneous administration.

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

4.7 Use during pregnancy, lactation or lay

The product can be administered during pregnancy in cows (for information on use in lactating animals, see section 4.11).

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 should be given only by subcutaneous injection at the recommended dosage level of 2 mg ivermectin per 10 kilogram bodyweight. Each ml contains 10 mg of ivermectin. Inject under the loose skin in front of or behind the shoulders. The injection may be given with any standard automatic, multidose or single dose hypodermic syringe.

Cattle: 1 ml per 50 kg bodyweight.

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)

Cattle must not be slaughtered for human consumption until 49 days after the last treatment.

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.

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 ligandgated 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal

6.2 Incompatibilities

In the absence of compatibility 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 200ml, 500ml and 1000ml colourless LDPE plasticflasks sealed with a rubber Type I bung, secured with an aluminium seal.

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

Any unused product or waste material should be disposed of in accordance with national requirements. Ivermectin is EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Treated animals should not have direct access to surface waters or ditches. Do not contaminate surface waters or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue – 2065m – LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER(S)

VPA 10988/105/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/09/1999

10 DATE OF REVISION OF THE TEXT

08/03/2024