1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec 10 mg/ml Injectable Solution for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Ivermectin 10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Glycerol formal	q.s. 1 ml

Clear, slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product 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

The veterinary medicinal product 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 the veterinary medicinal product 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 the veterinary medicinal product, 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.

3.3 Contraindications

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

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 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.

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 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.

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 results are reported in dogs – especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Discomfort[1] Injection site swelling[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

Pregnancy:

Can be used during pregnancy in cows (for information on use in lactating animals, see section 3.12).

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use.

The veterinary medicinal product 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 a correct dosage, body weight 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.
The use of suitably calibrated measuring equipment is recommended.

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

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

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

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: 49 days.
Not authorised for use in animals producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant dairy heifers, within 60 days of calving.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

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. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

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: 3 months.

5.3. Special precautions for storage

Store below 30 °C.

5.4 Nature and composition of immediate packaging

Supplied in 200 ml, 500 ml and 1000 ml colourless LDPE plastic vials sealed with a rubber Type I bung, secured with an aluminium seal.

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. 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.

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 S.A

7. MARKETING AUTHORISATION NUMBER(S)

VPA10988/105/001

8. DATE OF FIRST AUTHORISATION

07/09/1999

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

17/12/2024

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).