SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec super 10 mg/ml / 100 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Ivermectin ..... 10 mg
Clorsulon ..... 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Propyl gallate (E310)	0.2 mg
Disodium edetate	
Glycerol formal	
Propylene glycol	
Water for injections	

Clear, slightly yellow and slightly viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the treatment of mixed trematode and nematode or arthropod infestations, due to adult and immature roundworms, lungworms, warbles, mites, lice and liver fluke in cattle.

Gastro-intestinal roundworms (adult and fourth-stage larvae):
Ostertagia ostertagi (including inhibited larval stages)
O. lyrata
Haemonchus placei
Trichostrongylus axei

Trichostrongylus colubriformis
Cooperia oncophora
Cooperia punctata
Cooperia pectinata
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
Nematodirus spathiger (adult)

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

Liver fluke (adult):
Fasciola hepatica

Warbles (parasitic stages):
Hypoderma bovis
Hypoderma lineatum

Mange mites:
Psoroptes bovis
Sarcoptes scabiei var. *bovis*

Sucking lice:
Linognathus vituli
Haematopinus eurysternus

The veterinary medicinal product may also be used as an aid in the control of the mange mite *Chorioptes bovis*, but complete elimination may not occur.

3.3 Contraindications

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.
Not for use in species other than cattle as severe adverse reactions, including fatalities, may occur in dogs for example.
Do not use by the intravenous or intramuscular route.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

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 (if any).

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 macrocyclic lactones (which includes ivermectin) has been reported in *Ostertagia ostertagi* and *Cooperia spp*, in cattle within the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes 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:
Divide doses greater than 10 ml between two injection sites to reduce occasional discomfort or site reaction.

Frequent and repeated use may lead to the development of resistance.

The timing of treatment for the parasitic stages of warbles should be chosen carefully. The best time to treat against infections with *Hypoderma* is immediately after the end of the swarming of the warbles, before the larvae cause damage in the body of the animal (October to November). If larvae of *Hypoderma bovis* are killed during migration through the spine, this may induce posterior paralysis and recumbency. These reactions occur mainly when animals are treated between December and March.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the doctor.
Do not smoke, drink or eat while handling the veterinary medicinal product.
Wash hands after use.
Avoid contact with skin and eyes.
Take care to avoid self-administration, the veterinary medicinal product may cause irritation and/or pain at the site of injection.

Special precautions for the protection of the environment:
Ivermectin is highly toxic to aquatic invertebrates. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment to avoid adverse effects on aquatic organisms.

Other precautions:
Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or 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], Injection site pain[2,3] Hypersensitivity reaction[4]

[1]Transitory.
[2]Soft-tissue reactions, disappeared without treatment.
[3]Slight.
[4]Symptomatic treatment should be applied.

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 and lactation:
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

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 once by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin and 2 mg clorsulon per kilogram of bodyweight. Each ml contains 10 mg of ivermectin and 100 mg of clorsulon, sufficient to treat 50 kg of bodyweight. Subcutaneous injection only.

To ensure administration of a correct dose, 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 over-dosing.

Divide doses greater than 10 ml between two injection sites.
Inject under the loose skin behind the shoulder. Use of a 17 gauge, ½ inch (15-20 mm) needle is suggested. The injection may be given with any standard automatic,

multidose or single-dose hypodermic syringe. If using a hypodermic syringe, use a separate sterile needle to withdraw the dose from the pack.
This product does not contain an antimicrobial preservative. Swab septum before removing each dose.
Use a dry, sterile needle and syringe.
For 200, 500 and 1000 ml pack sizes, use only automatic syringe equipment.
Injection on animals with wet or dirty hides is not recommended.
When the temperature of the product is below 5°C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15°C will greatly increase the ease with which the product can be injected. Different injection sites should be used for other parenteral products.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.

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

An acute toxic syndrome consisting of CNS signs of depression and listlessness, ataxia, recumbency and possible death occurs in cattle given S.C. doses equal to 40 times the therapeutic dose for ivermectin. Treatment should be symptomatic.
A toxic-syndrome dose level has not been identified in cattle for clorsulon.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA51

4.2 Pharmacodynamics

Ivermectin is a broad spectrum endectocide of the avermectin family. Ivermectin is isolated after purification and hydrogenation of the avermectin family compounds which are obtained from the fermentation of the soil organism Streptomyces avermitilis.

Ivermectin is a macrocyclic-lactone derivative which has a broad and potent antiparasitic activity against nematodes and arthropods. It acts by inhibiting nerve impulses. Ivermectin 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."

Clorsulon inhibits glycolytic enzymes of *Fasciola hepatica* (3-phosphoglycerate kinase and phosphoglyceromutase). This enzymatic inhibition effectively blocks the Embden-Myerhof glycolytic pathway and thereby deprives the fluke of its main source of metabolic energy.

4.3 Pharmacokinetics

After subcutaneous injection of the product at the dose of 1 ml per 50 kg (200 µg/kg of ivermectin and 2 mg/kg of clorsulon), mean maximum concentrations of 26 ng/ml for ivermectin and 2.8 µg/ml for clorsulon were reached at 35 hours for ivermectin and 9 hours for clorsulon.

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: 28 days.

5.3 Special precautions for storage

Store in the original container.
Protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box containing 200 ml, 500 ml and 1000 ml colourless LDPE vials with plastic overcap covering rubber stopper and aluminium overseal.

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.

This veterinary medicinal product should not enter water courses as ivermectin and clorsulon is extremely dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty 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

7. MARKETING AUTHORISATION NUMBER

Vm 05653/4155

8. DATE OF FIRST AUTHORISATION

15 December 2011

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

May 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Approved 14 May 2026
Gavin Hall