SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERMECTIN AND CLORSULON 10 mg/ml / 100 mg/ml Solution for Injection for Cattle Virbac

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Ivermectin	10	mg/ml
Clorsulon	100	mg/ml

Excipient(s):

Propyl gallate (E310) …….	0.2	mg/ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, slightly yellow and slightly viscous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the 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 viviparus
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 product may also be used as an aid in the control of the mange mite *Chorioptes bovis*, but complete elimination may not occur.

4.3 Contraindications

Do not use in cattle producing milk for human consumption.
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 animals known to be hypersensitive to the active substance.

4.4 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.

4.5 Special precautions for use

i. Special precautions for use in animals

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.

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.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Do not smoke, drink or eat while handling the product. Wash hands after use.
Avoid contact with skin and eyes.
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)

Transitory discomfort has been observed in some cattle following subcutaneous administration. Soft-tissue swelling and/or slight pain at the injection site has also been observed. These reactions have disappeared without treatment.
In case of hypersensitivity reactions a symptomatic treatment should be applied.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by ivermectin.

4.9 Amounts to be administered and administration route

The 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.

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.

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

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.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: endectocide, anthelmintic *Flukicide.*
ATCvet code: QP54AA51

5.1 Pharmacodynamic properties

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."

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl gallate
Disodium
Edetate Water
for injections
Glycerol formal
Propylene glycol

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 : 36 months. Shelf-life after first opening the immediate packaging : 28 days.

6.4 Special precautions for storage

Protect from light.
Store in the original container.
Following withdrawal of the first dose, use the product within 28 days.

6.5 Nature and composition of immediate packaging

Size 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.

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

Any unused product or waste material should be disposed of in accordance with national requirements.
EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/5059

9. DATE OF FIRST AUTHORISATION

17 September 2004

10. DATE OF REVISION OF THE TEXT

December 2023

Approved 01 December 2023