SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Super Injection for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Ivermectin 10 mg
Clorsulon 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol formal
Propylene Glycol

A clear, slightly yellow coloured 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 the treatment and control of the following parasites:

Gastrointestinal roundworms (adult and fourth-stage larvae):
Ostertagia ostertagi (including inhibited larval stages)
O. lyrata
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata
C. pectinata
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
N. spathiger (adult)

Trichuris spp. (adult)

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

Liver fluke (adult):
Fasciola hepatica

Eye worms (adult):
Thelazia spp.
Warbles (parasitic stages):
Hypoderma bovis
H. lineatum

Mange mites:
Psoroptes bovis
Sarcoptes scabiei 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 biting lice *(Damalinia bovis)* and the mange mite (*Chorioptes bovis),* but complete elimination may not occur.

Persistent Activity
The veterinary medicinal product given at the recommended dosage of 0.2 mg per kg bodyweight controls re-infection with *Haemonchus placei, Cooperia* spp. and *Trichostrongylus axei* acquired up to 14 days after treatment; *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by a qualified professional person.

3.3 Contraindications

Do not use intramuscularly or intravenously.
The veterinary medicinal product is a low-volume product registered for use in cattle. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

For use only in beef cattle and non-lactating dairy cattle.

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 bodyweight, 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 macrocyclic lactones (which includes ivermectin) has been reported in *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:
This product does not contain any antimicrobial preservative.
Swab septum before removing each dose.
Special precautions to be taken by the person administering the veterinary medicinal product to the animals:
Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use.
Take care to avoid self-administration as the veterinary medicinal product may cause local irritation and/or pain at the injection site.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1], discomfort[1]

[1] following subcutaneous injection, resolves 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 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:
The veterinary medicinal product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

Fertility:
The veterinary medicinal product
will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous.
The veterinary medicinal product should be administered only by subcutaneous injection at the recommended dosage level of 1 ml/50 kg bodyweight (based on a dosage level of 200 mcg ivermectin plus 2 mg clorsulon per kg bodyweight) under the loose skin in front of, or behind, the shoulder. Divide doses greater than 10 ml between two injection sites. A sterile 17-gauge 1/2 inch (15-20 mm) needle is recommended. Replace with a fresh sterile needle after every 10-12 animals or sooner if the needle becomes soiled. To ensure a correct dosage, bodyweight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

When the temperature of the veterinary medicinal product is below 5 °C, difficulty in administration may be encountered due to increased viscosity.

Warming the veterinary medicinal product and injection equipment to about 15 °C will greatly increase the ease with which the veterinary medicinal product can be injected. Different injection sites should be used for other parenteral products administered concurrently.

When using the 200 ml, 500 ml and 1000 ml pack sizes, only use automatic syringe equipment. For the 50 ml pack sizes, use of a multidose syringe is recommended.

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

The administration of 25 ml of the veterinary medicinal product per 50 kg bodyweight (25x the recommended dose level) resulted in an injection site lesion (including tissue necrosis, oedema, fibrosis and inflammation). No other drug-related adverse reactions could be determined.

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.
Milk: 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA51

4.2 Pharmacodynamics

Ivermectin:

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind 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 hyperpolarisation of the nerve or muscle cell, resulting in paralysis and death of the parasite. 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:

Clorsulon is rapidly absorbed into the circulating blood. Erythrocytes with bound drug as well as plasma are ingested by *Fasciola* spp. Adult *Fasciola* spp. are killed by clorsulon because of inhibition of enzymes in the glycolytic pathway, which is their primary source of energy.

4.3 Pharmacokinetics

Maximum plasma concentration

After subcutaneous administration of 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight, the plasma profile demonstrated the slow, steady absorption of ivermectin with peak plasma levels averaging 23 ng/ml around day 7 post dose. In contrast, clorsulon appeared rapidly absorbed since the first sampling point, 8 hours post dose, had the highest average residues, approximately 2 µg/ml.

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: 5 years.
Shelf-life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Protect from light.

5.4 Nature and composition of immediate packaging

Multiple-dose rubber-capped polyethylene bottles of 50 ml, 200 ml, 500 ml and 1000 ml. Bottles are stoppered and then either sealed by heat or crimp-sealed with an aluminium cap.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the veterinary medicinal product or used containers.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste material 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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 61700/5020
Vm 61700/3031

8. DATE OF FIRST AUTHORISATION

27 August 1987

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

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 02 December 2025