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 substance:

Ivermectin	10	mg
Clorsulon	100	mg

For a full list of excipients, see section 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

Ivomec Super Injection for Cattle is indicated for the treatment and control of the following parasites:

Gastrointestinal roundworms (adult and fourth-stage larvae):
Ostertagia spp. (including inhibited *O. ostertagi*)
Haemonchus placei
Trichostrongylus axei
T.colubriformis
Cooperia spp.
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult only)
Nematodirus helvetianus (adult only)
N. spathiger (adult only)
Toxocara vitulorum
Trichuris spp. (adult only)

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

Ivomec Super Injection for Cattle 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
When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with Ivomec Super Injection for Cattle at the recommended dose rate can control re-infection with *Haemonchus placei* and *Cooperia* spp., acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomumradiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of Ivomec Super Injection for Cattle in grazing animals, it is recommended that calves which are set-stocked in the 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

This product is not to be used intramuscularly or intravenously.

This product is registered for use in cattle only. Do not use in other species as severe adverse reactions, including fatalities, may occur.Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

Details provided above apply. See also points 4.2, 4.3 and 4.5.
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.

4.5 Special precautions for use

Special precautions for use in animals
Divide doses in excess of 10 ml between different injection sites and use different sites to those used for other parenteral medications
Swab septum before removing each dose.
Use dry sterile needle and syringe.
When using the 200 ml and 500 ml pack sizes, use only automatic syringe equipment.
For the 50 ml pack size, the use of a multidose syringe is recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not smoke or eat while handling the product.
Wash hands after use.Take care to avoid self-administration; the product may cause local 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. A low incidence of soft tissue swelling at the injection site has been observed. These reactions disappeared without treatment.

4.7 Use during pregnancy, lactation or lay

Ivomec Super Injection for Cattle is safe for use at any stage of pregnancy or lactation. However, the product is not permitted for use in animals producing milk for human consumption,including pregnant animals intended to produce milk for human consumption.Ivomec Super Injection for Cattle will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

4.8 Interaction with other medicinal products and other forms of interactions

No interactions have been identified with other products.

4.9 Amounts to be administered and administration route

Ivomec Super Injection for Cattle should be given 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.To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
A sterile 17 gauge ½ inch (15-20mm) needle is recommended. Replace with a fresh sterile needle after every 10-12 animals or sooner if the needle becomes soiled.
When the temperature of the
product is below 5^{o}C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15^{o}C will greatly increase the ease with which the product can be injected. Different injection sites should be used for other parenteral products.

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

The administration of 25 ml Ivomec Super Injection for Cattle per 50 kg bodyweight (25 x the use level) resulted in injection site lesion (including tissue necrosis, oedema, fibrosis and inflammation). No other drug-related adverse reactions could be determined.

4.11 Withdrawal period(s)

Cattle intended for human consumption may not be slaughtered until 66 days after the last treatment.
Not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides
ATCvet code: QP54AA51

5.1 Pharmacodynamic properties

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 hyperpolarization 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.

5.2 Pharmacokinetic particulars

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.

Excretion: length of time and route
A dose rate of 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight was administered by subcutaneous injection. For ivermectin, liver had the highest average residues, peaking on day 7 post dose at an average of 220 ppb. Depletion followed so that by days 28 and 35 the liver residues were 11 and 6 ppb respectively. Fat residues also peaked on day 7 at an average of 160 ppb. They decreased to 6 and 4

ppb by days 28 and 35. Muscle and kidney residues were negligible at 1 and 2 ppb respectively by day 28.

For clorsulon, kidney had the highest average residues of 0.54 ppm (540 ppb) on day 3 post dose. At the same time, liver averaged 0.20 ppm, muscle averaged 0.06 ppm and fat averaged 0.02 ppm. Rapid depletion followed, resulting in average residues at or below the detection limit of 0.01 ppm by day 21 for all tissues.

In cattle receiving a single dose of tritium-labelled ivermectin (0.2-0.3 mg/kg bodyweight), analyses show that composites of faeces collected during the first 7 days after dosing contained almost all the dosed radioactivity, only about 1-2% being excreted in the urine. Analyses of the faeces showed that about 40-50% of the excreted radioactivity was present as unaltered drug. The remaining 50-60% was present as metabolites or degradation products, almost all of which were more polar than the ivermectin.
During the first 7 days following intrarumen administration of 7 mg/kg clorsulon to a 270 kg steer, about 90% of the radiolabel in an administered dose was found in both the urine (25%) and the faeces (65%).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal
Propylene Glycol

6.2 Major incompatibilities

In the absence of compatability 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: 5 years
Shelf-life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage

Protect from direct sunlight. Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

Multiple-dose rubber-capped polyethylene bottles of 50 ml, 200 ml and 500 ml containing a sterile non-aqueous solution. Not all pack sizes may be marketed.

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

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Do not contaminate lakes or streams as free ivermectin may adversely affect fish and certain water-borne organisms.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/068/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1994
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

July 2018