1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Classic Injection for Cattle and Sheep 10 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Ivermectin 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol Formal
Propylene Glycol

Clean, clear, pale straw-coloured liquid, free from visible evidence of contamination

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the effective treatment and control of the following harmful species of gastro-intestinal roundworms, lungworms, eye worms, warbles, lice and mange mites of cattle and sheep:

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

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

Eye worms (adult):
Thelazia spp.

Warbles:
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.

Prolonged Activity
When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with the veterinary medical product 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 *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of the veterinary medicinal product for 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 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.

Sheep
Mange mites:
*Psoroptes ovis**

*For the treatment and control of sheep scab, two injections with a seven-day interval are required to treat clinical signs of scab to eliminate mites.

Gastrointestinal roundworms (adult and fourth-stage larvae):
Ostertagia circumcincta including inhibited larvae
O. trifurcata
Haemonchus contortus including inhibited larvae
Trichostrongylus axei (adults)
T. colubriformis and *T. vitrinus* (adults)
Cooperia curticei Oesophagostomum columbianum
O. venulosum (adults) *Nematodirus filicollis*
Chabertia ovina
Trichuris ovis (adults)

Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.

Lungworms:
Dictyocaulus filaria (adult and fourth-stage larvae)
Protostrongylus rufescens (adults)

Nasal bots (all larval stages):
Oestrus ovis.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
This veterinary medicinal product is not for intramuscular or intravenous use.

3.4 Special warnings

In sheep treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although a clinical improvement may be seen, elimination of all mites may not occur.
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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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 veterinary medical product may cause local irritation and/or pain at the site of injection.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
This veterinary medicinal product has been formulated specifically for use in these target species. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1], Injection site pain[2]

[1] Soft tissue. Dissappears without treatment.
[2] Transient.

Sheep:

Very rare	Injection site pain[1]

(<1 animal / 10,000 animals treated, including isolated reports):	

[1] Sometimes intense but usually transient.

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:
This veterinary medicinal product can be administered to beef cows and ewes at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.

Fertility:
This veterinary medicinal product will not affect the fertility of cows, bulls, breeding ewes and rams and can be given to all ages of animals including young calved and lambs.

3.8 Interaction with other medicinal products and other forms of interaction

This veterinary medicinal product has been used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.
Adequate vaccination of sheep against clostridial infections is strongly recommended.

3.9 Administration routes and dosage

Subcutaneous use.
This veterinary medical product should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle and over the neck in sheep. To ensure a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle and sheep. The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 17 gauge x ½ inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended. If using a single-dose or hypodermic syringe, use a separate sterile needle to withdraw the veterinary medical product from the pack.

For the treatment and control of sheep scab (*Psoroptes ovis*), two injections with a seven-day interval are required to treat clinical signs of scab and to eliminate mites.

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

Cattle
Single doses of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.

Sheep
At dose levels up to 4 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.
No antidote has been identified; however, symptomatic therapy may be beneficial.

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

Cattle
Meat and offal: 49 days.
Milk: Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Sheep:
Meat and offal: 22 days.
Milk: Do not use in lactating sheep producing milk for human consumption. Do not use in sheep within 60 days of lambing where milk is to be used for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Maximum plasma concentration

Cattle:
At a dose level of 0.2 mg ivermectin per kg a maximum plasma concentration of 35-50 ng/ml is reached in +/- 2 days and the half-life in plasma is of 2.8 days. It is also established that ivermectin is carried mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.

Sheep:
At a dose level of 0.3 mg ivermectin per kg an average peak of 16 ng/ml is reached one day after injection.

Excretion: length of time and route

Cattle:
A liquid chromatographic method with fluorescence detection allows the determination of ivermectin residues in tissues. After an injection of 0.3 mg ivermectin per kg, the liver (target tissue) had residues ranging from 454 ppb at 2 days post treatment to 11 ppb at 28 days post treatment. All other tissues

had lower residues at all time periods: fat > kidney > muscle. The injection site had residues shortly after treatment, ranging up to 69 ppm at 2 days withdrawal, but by 28 days the average residue was negligible (<2 ppb). Cattle receiving a single dose of
tritium-labelled ivermectin (0.2 - 0.3 mg/kg bodyweight) were slaughtered at 7, 14, 21 and 28 days after dosing. Composites of faeces collected during the first 7 days after dosing contained almost all the dosed radioactivity. Only about 1-2% of the dosed radioactivity was 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 which were more polar than the ivermectin.

Sheep:
A liquid chromatographic method with fluorescence detection allows the determination of ivermectin residues in tissues. After an injection of 0.3 mg ivermectin per kg, the liver (target tissue) had residues ranging from 160 ppb at 3 days post treatment to 7.2 ppb at 28 days post treatment. The highest residue levels were recovered in fat (from 230 ppb at 3 days post treatment to 13 ppb at 28 days post treatment). Residues in all tissues were below 30 ppb at 28 days post treatment. Radioactive ivermectin was administered to sheep at a dose rate of 0.3 mg per kg.
Analyses of the faeces showed that about 99% of the drug and its metabolites are excreted in the faeces, +/- 1% being excreted in the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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: 3 months.

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from light.

5.4 Nature and composition of immediate packaging

50ml, 200ml, 500ml colourless low density polyethylene multidose bottle with butyl rubber closure.
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.
Studies indicate that when ivermectin comes in contact with soil, it readily and tightly binds to the soil and becomes inactive. The veterinary medical product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/064/001

8. DATE OF FIRST AUTHORISATION

01 October 1994

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

14 February 2025

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).