Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Classic Pour-On for Cattle 5 mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance
Ivermectin 5 mg
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pour-on solution
A clear, slightly yellow coloured solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

IVOMEC Classic Pour-On provides an effective control of the following pathogenic species of parasites of cattle:

Gastrointestinal roundworms:
Ostertagia ostertagi adults & immatures*
(including inhibited stage)
Haemonchus placei adults & immatures*
Trichostrongylus axei adults & immatures*
T. colubriformis adults & immatures*
Cooperia spp. adults & immatures*
Oesophagostomum radiatum adults & immatures*
Strongyloides papillosus adults
Trichuris spp. adults

Lungworms:
Dictyocaulus viviparus adults & immatures*

*Fourth-stage larvae.

Eyeworms:
Thelazia spp. adults

Warbles (parasitic stages):
Hypoderma bovis
H. lineatum

Mites:
Sarcoptes scabiei var. bovis
Chorioptes bovis

Lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Damalinia bovis

IVOMEC Classic Pour-On given at the recommended dosage of 500 micrograms per kg bodyweight, controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment and *Dictyocaulus viviparus* (lungworm) acquired during the first 28 days after treatment.
It also controls horn fly (*Haematobia irritans*) for up to 35 days after treatment.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
This product is for application to skin surface only, do not give orally or parenterally.

4.4 Special warnings for each target species

Cattle should not be treated when hair or hide is wet. Rain falling on cattle in less than two hours after dosing may result in reduced efficacy. However, the efficacy of the product against established infections of *O. ostertagi* or *D. viviparus* is not adversely affected if the hide is wet or if rain falls shortly after treatment.
Do not apply to areas of skin which may have mange scabs or other lesions or to areas contaminated with mud or manure.

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

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons.
Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use.
Use only in well-ventilated areas or outdoors.
As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

No undesirable effect has been identified when the product is used at the recommended dose rate.

4.7 Use during pregnancy, lactation or lay

IVOMEC Classic Pour-On can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. The product 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

The product may be used concurrently with foot and mouth disease vaccine or clostridial vaccine.

4.9 Amounts to be administered and administration route

For pour-on use.
Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 micrograms per kg bodyweight).
Administration: The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Dosing cup with Measure-Squeeze-Pour System (250 ml bottle and 1 litre pack)

The 250 ml pack contains one 25 ml dosing cup and one dip tube.
The 1 litre pack contains one 60 ml dosing cup and one dip tube.

Insert the dip tube into base of the dosing cup. Leave the "slotted end" of the dip tube exposed in the bottom of the bottle. Unscrew bottle cap from the top of the bottle. Screw the dosing cup onto the top of the bottle.

Measure: To select the correct dose rate, rotate the adjuster cap at the top of the cup in either direction to position the dose indicator to the weight of the animal you want to treat. When body weight is between markings, use the higher setting.

Squeeze the bottle gently to fill the dosing cup to the required dose. Release your grip and any excess will return to the bottle.

Pour: Apply the full dose by tipping and pouring along the back line of the animal until the dosing cup is empty.

The dosing cup should not remain attached to the bottle when not in use. Detach the dosing cup after each use and replace the bottle cap.

Collapsible Pack (2.5 litre pack)

Connect the pour-on applicator to the collapsible pack as follows:

•Attach the open end of the draw-off tubing to the pour-on applicator.**
•Attach draw-off tubing to the cap with the stem. Replace the shipping cap with the cap that has the draw-off tubing. Tighten this draw-off cap.
•Gently prime the pour-on applicator, checking for leaks.
•Follow manufacturer's directions for correct use and care of the equipment.

**An applicator compatible with the formulation is available for use with the 2.5 litre pack of IVOMEC Classic Pour-On. Other applicators may be incompatible with the formulation, resulting in locking, incorrect dosage and leakage.

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

No sign of toxicity appeared up to 5 mg/kg (10 times the recommended dose rate). No antidote has been identified.

4.11 Withdrawal period(s)

Meat and offal: 15 days.
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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, endectocides, macrocyclic lactones, avermectins; ivermectin
ATC vet code: QP54AA01

5.1 Pharmacodynamic properties

Mechanism of Action

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.

5.2 Pharmacokinetic particulars

Maximum plasma concentration
After topical administration of 0.5 mg ivermectin per kg bodyweight, the plasma samples averaged 1 ng/ml 8 hours post treatment and on days 1 through 7 post

dose the average plasma residues were reasonably constant at approximately 3 ng/ml. After day 7 the ivermectin residues gradually decreased to an average of 2 ng/ml at 14 days and 1 ng/ml at 28 days. The concentrations mentioned relate to the main compound of ivermectin, 22,23-dihydroavermectin B_{1a}.

Excretion: length of time and route
After topical administration of 0.5 mg ivermectin per kg bodyweight, liver, the target tissue, generally had the highest residues, averaging 48 ppb at 7 days post dose, 12 ppb at Day 28, and 0 at Day 56. Fat residues averaged 29 ppb at 7 days, 9 ppb at 28 days and 1 ppb on Day 56 after treatment. The dose site residues averaged 13 ppb at Day 7 and dropped to 5 ppb by Day 35. The excretion occurs mainly through faeces and, in a lesser proportion, *via* urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trolamine
Crodamol CAP Isopropyl Alcohol

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Flammable - keep away from heat, sparks, open flame or other sources of ignition.
Protect from light.
Bottles should remain upright during storage. The dosing cup should not be stored attached to the bottle when not in use. Remove the cup after each use and replace with the bottle cap. Cloudiness may result when the product is stored at temperatures below 0°C. Allowing the product to warm at room temperature will restore the normal appearance without affecting efficacy.

6.5 Nature and composition of immediate packaging

Polyethylene bottles of 250 ml and 1 L.
The 250 ml bottle is provided with one 25 ml dosing cup and one dip tube. The 1 L bottle is providd with one 60 ml dosing cup and one dip tube.

Collapsible pack of 2.5 L.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Do not contaminate lakes and streams with unused product or waste material 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)

VPA10454/065/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th March 2000
Date of last renewal: 29th March 2005

10 DATE OF REVISION OF THE TEXT

July 2018