# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panomec 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active Substance**
Ivermectin 10 mg

**Excipients**
Glycerol formal 0.4 ml

For a full list of excipients, see Section 6.1

## 3 PHARMACEUTICAL FORM

Solution for injection.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle, sheep and pigs.

### 4.2 Indications for use, specifying the target species

For the effective treatment and control of the following species of gastro-intestinal roundworms, lungworms, grubs, lice and mange mites of cattle, sheep and pigs:

***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 viviparous*

**Eye worms** (adult):
*Thelazia* spp.

**Warbles:**
*Hypoderma bovis*
*H. lineatum*

**Mange mites:**
*Psoroptes bovis*
*Sarcoptes scabiei* var. *bovis*

**Suckling lice:**
*Linognathus vituli*
*Haematopinus eurysternus*
*Solenopotes capillatus*

This 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 this 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 this 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 gastroenteritis 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 and to eliminate mites.

**Sheep parasites:**

**Gastrointestinal roundworms** (adult and fourth-stage larvae):
*Ostertagiacircumcincta* including inhibited larvae
*O. trifurcata*
*Haemonchus contortus* including inhibited larvae
*Trichostrongylus axei* (adults)
*T. colubriformis* and *T. vitrinus* (adults)
*Cooperiacurticei*
*Oesophagostomum columbianum*
*O. venulosum* (adults)
*Nematodirus filicollis*
*Chabertia ovina*
*Trichurisovis* (adults).

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

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

**Nasal Bots** (all larval stages)
*Oestrus ovis*
*Pigs*

**Gastrointestinal roundworms** (adult and fourth-stage larvae):
*Ascaris suum*
*Hyostrongylus rubidus*
*Oesophagostomum* spp.
*Strongyloides ransomi* (adult and somatic larval stages)

**Lungworms:**
*Metastrongylus* spp. (adults)

**Lice:**
*Haematopinus suis*

**Mange mites:**
*Sarcoptes scabiei* var. *suis*

## 4.3 Contraindications

Do not use in case of hypersensitivity to the active substance.
Do not administer by intramuscular or intravenous routes.

## 4.4 Special warnings for each target species

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.

## 4.5 Special precautions for use

### Special precautions for use in animals

Panomec 10 mg/ml Solution for Injection for Cattle, Sheep and Pigs 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.

### 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.
Avoid the introduction of contamination during use.

## 4.6 Adverse reactions (frequency and seriousness)

**Cattle**
Mild and transient discomfort has occasionally been observed in cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed.

**Sheep**
Discomfort, sometimes intense but usually transient, has been observed in some sheep following subcutaneous administration.

**Pigs**
Mild and transient discomfort has occasionally been observed in pigs following subcutaneous injection.

All these reactions disappeared without treatment.

## 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

## 4.8 Interaction with other medicinal products and other forms of interaction

This 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.

## 4.9 Amounts to be administered and administration route

For subcutaneous use only.
Administer by subcutaneous injection at the recommended dosage level of 200 microgram ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle and over the neck in sheep.
At the recommended dosage level of 300 microgram ivermectin per kg of bodyweight, administer by subcutaneous injection in the neck of pigs.
Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle and sheep and 33 kg of bodyweight of pigs. 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 product from the pack.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accurancy of the dosing device should be checked.
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.
In young pigs, especially those below 16 kg for which less than 0.5 ml of the product is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

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

**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.

**Pigs**
A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneouly to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.

No antidote has been identified; however, symptomatic therapy may be beneficial.

**4.11 Withdrawal period(s)**

**Cattle**
Meat and offal: 49 days.
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.
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.

**Pigs**
Meat and offal:14 days.

## 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***

**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 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 of 0.3 mg ivermectin per kg an average peak of 16 ng/ml is reached one day after injection.

**Pigs**
During trials carried out at a dose rate of 0.2 mg/kg ivermectin, a plasma concentration of 10-20 ng/ml was reached in +/- 2 days and half-life in plasma was 0.5 day.

***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 body weight) 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.

**Pig**
A liquid chromatographic method with fluorescence detection allows the determination of ivermectin residues in tissues. After an injection of 0.4 mg/kg ivermectin the liver (target tissue) contained average residues ranging from 69 ppb at 3 days post dose to 13 ppb at 14 days post dose. No liver residue (< 2 ppb) was found at 28 days post dose. Swine receiving a single dose of tritium-labelled ivermectin (0.3-0.4 mg/kg) were slaughtered at 1, 7, 14 and 28 days after dosing. Composites of faeces collected during the first 7 days after dosing contained only about 36% of the dosed radioactivity. Less than 1% of the dosed radioactivity was found in the urine. Analysis of the faeces showed that about 40% of the excreted radioactivity was unaltered drug.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glycerol formal
Propylene Glycol

### 6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with any other veterinary medicinal product.

### 6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
60 months

Shelf life after first opening the immediate packaging:
3 months

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

Multiple-dose rubber capped polyethylene bottles containing 50 ml, 100 ml, 200 ml or 500 ml of a pale yellow 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)

VPA10454/073/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th December 1995
Date of last renewal: 8th October 2010

## 10 DATE OF REVISION OF THE TEXT

May 2018