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Panomec Injection for Cattle, Sheep and Pigs

Species: Cattle, Pigs, Sheep

Therapeutic indication:Pharmaceuticals: Endoparasiticides: Anthelmintics for cattle, Anthelmintics for sheep, Anthelmintics for pigs, **Pharmaceuticals: Ectoparasiticides:** For cattle, For sheep, For pigs, **Pharmaceuticals: Endectocides:** For cattle, For sheep, For pigs

Active ingredient: Ivermectin

Product: Panomec Injection for Cattle, Sheep and Pigs

Product index: Panomec Injection

Cattle - milk: See note

Cattle - meat:49 days

Sheep - meat:37 days

Pig - meat:19 days

Withdrawal notes: Do not use in cattle producing milk for human consumption and in non-lactating dairy cows including pregnant heifers within 60 days of calving. Do not use in sheep producing milk for human consumption.

Incorporating:

Qualitative and quantitative composition

Each ml contains:

Ivermectin 10 mg

Excipients: Glycerol formal & propylene glycol.

Pharmaceutical form

Solution for injection.

Appearance: a clear, pale, straw-coloured liquid.

Clinical particulars

Target species

Cattle, sheep and pigs.

Indications for use

The veterinary medicinal product is indicated for the effective treatment and control of the following harmful parasites of cattle, sheep and pigs:

Cattle

Gastrointestinal Roundworms (Adult, L4 and Inhibited L4)

Ostertagia ostertagi

Gastrointestinal Roundworms (Adult and L4)

Ostertagia lyrata

Cooperia oncophora

C. pectinata

C. punctata

Haemonchus placei

Trichostrongylus axei

T. colubriformis

Bunostomum phlebotomum

Oesophagostomum radiatum

Gastrointestinal Roundworms (Adult)

Strongyloides papillosus

Nematodirus helvetianus

Nematodirus spathiger

Trichuris spp.

Lungworms (Adult and L4)

Dictyocaulus viviparus

Eye Worms (Adult)

Thelazia spp.

Warbles

Hypoderma bovis

H. lineatum

Mange Mites

Psoroptes ovis

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 Barbers pole worm (*Haemonchus placei*), Small intestinal worm (*Cooperia* spp.) and Hairworm (*Trichostrongylus axei*) for 14 days, Brown stomach worm (*Ostertagia ostertagi*) and Nodular worm (*Oesophagostomum radiatum*) for 21 days, and Lungworm (*Dictyocaulus viviparus*) for 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.

Sheep

Gastrointestinal Roundworms (Adult, L4 and Inhibited L4)

Ostertagia circumcincta

Haemonchus contortus

Gastrointestinal Roundworms (Adult and L4)

Ostertagia trifurcata

Trichostrongylus colubriformis

Cooperia curticei

Oesophagostomum columbianum

Nematodirus filicollis

NOAH Compendium

Chabertia ovina

Gastrointestinal Roundworms (Adult)

Trichostrongylus axei

T. vitrinus

Oesophagostomum venulosum

Trichuris ovis

Lungworms (Adult and L4)

Dictyocaulus filaria

Lungworms (Adult)

Protostrongylus rufescens

Nasal Bots

Oestrus ovis

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.

Pigs

Gastrointestinal Roundworms (Adult and L4)

Ascaris suum

Hyostrongylus rubidus

Oesophagostomum spp.

Gastrointestinal Roundworms (Adult and somatic larval stages)

Strongyloides ransomi

Lungworms (Adult)

Metastrongylus spp.

Lice

Haematopinus suis

Mange Mites

Sarcoptes scabei var. suis

Contra-indications

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

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 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 *Teladorsagia* spp. in sheep and 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.

Special precautions for safe use in the target species

The 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.

Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasites of sheep. Following treatment of infected sheep, great care must be taken to avoid re-infestation, as mites may be viable for up to 15 days off the sheep. It is important to ensure all sheep which have been in contact with infected sheep are treated. Contact between treated infected and non-treated, non-infected flocks must be avoided until at least 7 days after the last treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Do not smoke, eat or drink while handling the veterinary medicinal product. Wash hands after use. Take care to avoid self-injection as the veterinary medicinal product may cause local irritation and/or pain at the injection site. In case of accidental self-injection, seek medical advice and show the label or package leaflet to the physician.

Adverse events

Cattle

Rare (1 to 10 animals / 10,000 animals treated): Injection site swelling (soft tissue)1

Very rare (<1 animal / 10,000 animals treated, including isolated cases): Discomfort2

1 disappears without treatment 2 transient after subcutaneous administration

Sheep

Very rare (<1 animal / 10,000 animals treated, including isolated cases): Pain1

1 sometimes intense but usually transient; disappears without treatment

Pigs

Very rare (<1 animal / 10,000 animals treated, including isolated cases): Pain1

1 mild and transient; disappears 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.

Use during pregnancy, lactation or lay

The 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, and to sows at any stage of pregnancy or lactation. The veterinary medicinal product will not affect the fertility of breeding ewes, rams, sows and boars. The veterinary medicinal product can be given to all ages of animals including young calves, lambs and piglets.

Interactions

The 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.

Administration routes and dosage

The veterinary medicinal 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 in the neck in sheep. At the recommended dosage level of 300 mcg ivermectin per kg bodyweight, the veterinary medicinal product should be given only subcutaneously in the neck in pigs.

Syringes must be filled from the vial through a dry sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than 20 times.

This product does not contain an antimicrobial preservative. Swab septum before removing each dose. Use sterile needle and syringe. When treating groups of animals use only an automatic dosing device (with vented draw-off apparatus when using the 50 ml vial). To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Use this chart as a guide in working out the appropriate dose rate:

Cattle (1 ml/50 kg)		**Sheep** (0.5 ml/25 kg)		**Pigs**
Bodyweight (kg)	Dose volume (ml)	Bodyweight (kg)	Dose volume (ml)	Body
Up to 50	1.0	Up to 5	0.1	Less
51-100	2.0	5.1-10	0.2	5-7
101-150	3.0	10.1-15	0.3	8-10
151-200	4.0	15.1-25	0.5	11-13
201-250	5.0	25.1-50	1.0	14-16
251-300	6.0	50.1-75	1.5	17-33
301-350	7.0	75.1-100	2.0	34-50
351-400	8.0			51-66
				67 - 9
				100 -
				134 -
				167 -
For cattle weighing over 400 kg calculate the dose at the rate of 1 ml per 50 kg bodyweight.		For sheep weighing over 100 kg calculate the dose at the rate of 0.5 ml per 25 kg bodyweight.		For p dose

When treating pigs and sheep of less than 16 kg, seek veterinary advice regarding the use of 1 ml disposable syringes graduated in increments of 0.1 ml. When treating individual sheep, a syringe, not exceeding 2 ml and calibrated in increments of 0.1 ml, should be used.

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. 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.

Overdose

Cattle: Single doses of 4 mg ivermectin per kg (20x the recommended use level) given subcutaneously resulted in ataxia and depression.

Sheep: At oral dose levels up to 4 mg ivermectin per kg (20x the recommended use level) given subcutaneously resulted in ataxia and depression.

Pigs: A dose of 30 mg ivermectin per kg (100x the recommended dose of 0.3 mg per kg) injected subcutaneously 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.

Withdrawal periods

Cattle (meat and offal): 49 days

Cattle (milk): Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

Sheep (meat and offal): 37 days

Sheep (milk): Do not use in lactating sheep producing milk for human consumption.

Pigs (meat and offal): 19 days.

Pharmaceutical particulars

Major incompatibilities

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

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.

Special precautions for storage

Protect from direct sunlight. Store below 30 °C. This product does not contain any antimicrobial preservative. Following withdrawal of the first dose, use the product within 6 months.

Immediate packaging

Multiple-dose rubber-capped polyethylene bottles of 50 ml, 200 ml and 500 ml containing a sterile non-aqueous solution for parenteral administration. Bottles are stoppered and then either sealed by heat or crimp-sealed with an aluminium cap.

Not all pack sizes may be marketed.

Disposal

Medicines should not be disposed of via wastewater. The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms. Do not contaminate surface waters or ditches with product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Marketing Authorisation Number

Vm 08327/4193

Significant changes

Legal category

Legal category:POM-VPS

GTIN

GTIN description: Panomec Injection for Cattle, Sheep and Pigs 50 ml

GTIN:3661103019398