

NOAH Compendium

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Ivomec Classic Injection for Cattle and Sheep

Species: Cattle, Sheep

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

Active ingredient: Ivermectin

Product: Ivomec Classic Injection for Cattle and Sheep

Product index: Ivomec Classic Injection

Cattle - milk: See note

Cattle - meat: 49 days

Sheep - meat: 37 days

Withdrawal notes: Do not use in cattle producing milk for human consumption. Do not use 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

Active substance: Each ml contains Ivermectin 10 mg.

Excipients: Glycerol formal & propylene glycol.

Pharmaceutical form

Solution for injection. A clear, pale, straw-coloured liquid.

Clinical particulars

Target species

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Cattle and sheep.

Indications for use

Indicated for the effective treatment and control of the following parasites of cattle and sheep:

Cattle

Gastrointestinal Roundworms (Adult, L4 and Inhibited L4)

Ostertagia ostertagi

Gastrointestinal Roundworms (Adult and L4)

Ostertagia lyrata

Cooperia oncophora

Cooperia pectinata

Cooperia punctata

Haemonchus placei

Trichostrongylus axei

Trichostrongylus 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

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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 Given at the recommended dosage of 1 ml per 50 kg bodyweight, the veterinary medicinal product controls re-infection with the following nematodes up to the duration shown: 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

Chabertia ovina

Gastrointestinal Roundworms (Adult)

Trichostrongylus axei

T. vitrinus

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Oesophagostomum venulosum

Trichuris ovis

Lungworms (Adult and L4)

Dictyocaulus filaria

Lungworms (Adult)

Protostrongylus rufescens

Nasal Bots

Oestrus ovis

Mange Mites

Psoroptes ovis

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

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 to any of the excipients.

Special warnings

In sheep, treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although 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 (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. 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

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The veterinary medicinal product has been formulated specifically for use in the target species. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur. When treating groups of animals use only an automatic dosing device (with vented draw off apparatus when using the 50 ml vial). 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.

Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasite of sheep. To ensure complete control 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 that all sheep which have been in contact with infected sheep are treated. Contact between treated, infected and untreated flocks must be avoided until at least seven days after treatment.

This product does not contain any antimicrobial preservative. Swab septum before removing each dose. Use a sterile needle and syringe.

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 site of injection. 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 reports): Discomfort²

¹disappears without treatment ²transient after subcutaneous administration

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports): Pain²

¹sometimes intense but usually 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. The veterinary

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medicinal product will not affect fertility of cows, bulls, breeding ewes and rams and can be given to all ages of animals including young calves and lambs.

Interaction with other medicinal products and other forms of interaction

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, using aseptic precautions, 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.

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)
Bodyweight (kg)	Dose Volume (ml)	Bodyweight (kg)
Up to 50	1.0	Up to 5
51-100	2.0	5.1-10
101-150	3.0	10.1-15
151-200	4.0	15.1-25
201-250	5.0	25.1-50
251-300	6.0	50.1-75
301-350	7.0	75.1-100
351-400	8.0	

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.

When treating sheep of less than 16 kg, seek veterinary advice regarding the use of 1 ml disposable syringes graduated in increments of 0.1 ml. For the treatment of individual sheep, a syringe not exceeding 2.0 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. The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of a sterile 17-gauge x ½ inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12

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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 medicinal 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 and to eliminate mites.

Symptoms of overdose

Cattle

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

Sheep

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

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

Withdrawal periods

Cattle (meat & 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 & offal): 37 days.

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

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

Store below 30 °C. Protect from direct sunlight. Following withdrawal of the first dose, use the product within 6 months.

Immediate packaging

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Multiple-dose rubber-capped polyethylene bottles of 50 ml, 200 ml, 500 ml and 1000 ml. Bottles are closed with grey butyl rubber bungs and then crimp-sealed with an aluminium cap. Not all pack sizes may be marketed.

Disposal

Medicines should not be disposed 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. Use take-back schemes for the disposal of any unused veterinary medicinal product or waste material derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Marketing Authorisation Number

Vm 08327/4188

Significant changes

Legal category

Legal category:POM-VPS

GTIN

GTIN description:Ivomec Classic Injection for Cattle & Sheep 200 ml

GTIN:3661103019329

GTIN description:Ivomec Classic Injection for Cattle & Sheep 500 ml

GTIN:3661103079404