PACKAGE LEAFLET

Oriverm 10 mg/mL solution for injection for cattle, sheep and pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Responsible for batch release:
Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oriverm 10 mg/mL solution for injection for cattle, sheep and pigs.
Ivermectin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 mL solution for injection contains:

Ivermectin 10 mg

A clear colourless to off-white liquid, free from visible particles.

4. INDICATION(S)

The product is indicated for the effective treatment and control of the spread of parasitic disease of the following parasites:"

Cattle:

Gastrointestinal roundworms
Ostertagia ostertagi (adults, L4, inhibited L4)
Ostertagia lyrata (adults, L4)
Haemonchus placei (adults, L4)
Trichostrongylus axei (adults, L4)
Trichostrongylus colubriformis (adults, L4)
Cooperia oncophora (adults, L4)
Cooperia punctata (adults, L4)
Cooperia pectinata (adults, L4)
Oesophagostomum radiatum (adults, L4)

Bunostomum phlebotomum (adults, L4)
Nematodirus helvetianus (adults)
Nematodirus spathiger (adults)
Strongyloides papillosus (adults)
Toxocara vitulorum (adults)
Trichuris spp. (adults)

Lungworms
Dictyocaulus viviparus (adults, L4, inhibited L4)

Eye worm
Thelazia spp. (adults)

Warbles (bot flies, parasitic stages)
Hypoderma bovis
Hypoderma lineatum

Mange mites
Psoroptes bovis
Sarcoptes scabiei var. bovis

Sucking lice
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

The product may also be used as an aid in the control and 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 product controls re-infection with the following nematodes up to the duration shown:

Parasite

Parasite	*No. of Days After treatment*
Haemonchus placei	*14*
Cooperia spp.	*14*
Trichostrongylus axei	*14*
Ostertagia ostertagi	*21*
Oesophagostomum radiatum	*21*
Dictyocaulus viviparus	*28*

Sheep:

Gastrointestinal roundworms
Haemonchus contortus (adults, L4, inhibited L4)
Teladorsagia (Ostertagia) circumcincta (adults, L4, inhibited L4)
Trichostrongylus axei (adults)

Trichostrongylus colubriformis (adults)
Trichostrongylus vitrinus (adults)
Nematodirus filicollis (adults, L4)
Nematodirus spathiger (L4)
Cooperia curticei (adults, L4)
Oesophagostomum columbianum (adults, L4)
Oesophagostomum venulosum (adults)
Chabertia ovina (adults, L4)
Trichuris ovis (adults)
Strongyloides papillosus (L4)
Gaigeria pachyscelis (adults, L4)

Lungworms
Dictyocaulus filaria (adults, L4)
Protostrongylus rufescens (adults)

Nasal bots
Oestrus ovis

Mange mites
Psoroptes communis var. ovis[*]
Sarcoptes scabiei
Psorergates (Psorobia) ovis

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

Pigs:

Gastrointestinal roundworms
Ascaris suum (adults, L4)
Hyostrongylus rubidus (adults, L4)
Oesophagostomum spp. (adults, L4)
Strongyloides ransomi[*] (adults, somatic larval stages)

Lungworms
Metastrongylus spp. (adults)

Kidney worm
Stephanurus dentatus (adults, L4, somatic larval stages)

Lice
Hamatopinus suis[**]

Mange mites
Sarcoptes scabei var. suis

[*]) Product given to sows 7 to 14 days before farrowing effectively controls transmission via the milk of *Strongyloides ransomi* infections to piglets.
[**]) Louse eggs are unaffected by ivermectin and may require up to 3 weeks to hatch. Louse infestations developing form hatching eggs may require re-treatment.

5. CONTRAINDICATIONS

The product should be administered only by the subcutaneous route and other routes are not authorised.
Do not use in animals with known hypersensitivity to ivermectin or to any of the excipients.
Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

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.

In both species these reactions disappear without treatment.

Pigs

Mild and transient pain reactions may be seen in some pigs following subcutaneous administration.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {*national system details*}.

7. TARGET SPECIES

Cattle, sheep and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Cattle and Sheep

The product should be given only by subcutaneous injection, using aseptic precautions, at the recommended dosage level of 200 µg of ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle and in the neck of the sheep.

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

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. 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, two injections with a seven-day interval are required to treat clinical signs of scab and to eliminate mites.

Pigs

At the recommended dosage level of 300 µg of ivermectin per kg bodyweight, administer only subcutaneously in the neck in pigs.

Each mL contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs.

9. ADVICE ON CORRECT ADMINISTRATION

The injection may be given with any standard automatic or single-dose or hypodermic syringe. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended.

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.

In young pigs, especially those weighing under 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 increments of 0.1 mL is recommended. For piglets weighing less than 16 kg give 0.1 mL/3 kg.

When treating pigs of less than 16 kg seek veterinary advice regarding the use of 1 mL disposable syringes graduated in increments of 0.1 mL.

Recommended treatment programme

Young animals and adults

Sows:
Treat prior to farrowing, preferably 7-14 days before, to minimize infection of piglets.

Gilts:
Treat 7-14 days prior to breeding. Treat 7-14 days prior to farrowing.

Boars:
Frequency of and need for treatments are dependent upon exposure.

To ensure the correct dose, determine the live weight of each animal as accurately as possible.

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 49 days.
Milk: Do not use in cattle producing milk for human consumption.

Sheep:
Meat and offal: 28 days.

Milk: Do not use in sheep producing milk for human consumption.

Pigs:
Meat and offal: 28 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after {EXP.}. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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).

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

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 antihelmintic 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 use in animals

When treating groups of animals use of an automatic dosing device (with vented draw off apparatus) is recommended when using the 100 mL vial.
Syringes must be filled from the vial through a dry sterile draw-off needle that has been placed in the vial stopper.

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.
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.

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:

- People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.
- The veterinary medicinal product should not be administered by pregnant women.
- Avoid contact with the skin and eyes. In case of skin or eye contact, immediately rinse affected area with water.
- Take care to avoid self-injection: the 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.
- Do not smoke, drink or eat while handling the product.
- Wash hands after use.

Other precautions regarding impact on the environment:

The product is very toxic to aquatic organisms and dung insects. Treated animals should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore, repeated treatment of animals on a pasture with an ivermectin-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

Pregnancy and lactation:

This product for cattle and sheep can be administered to cows and ewes at any stage of pregnancy or lactation provided that the milk is not intended for human consumption.
The product can be administered to sows at any stage of pregnancy or lactation.

Fertility:

It can be used in breeding ewes, rams, sows, boars, bulls and cows without affecting fertility. The product can be given to all ages of animals including young calves, lambs and piglets.

Interaction with other medicinal products and other forms of interaction:

Not data available.

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

Cattle
Single doses of 4.0 mg ivermectin/kg bodyweight (equal to 20 times the recommended dose) given subcutaneously resulted in ataxia and depression.

Sheep
Ivermectin administered subcutaneously has demonstrated adequate safety at the recommended dose level. At the oral dose of a commercial formulation an oral administration of up to 4mg ivermectin per kg (20 times the recommended dose) administered by a gastric tube did not cause undesirable toxic reactions.

Pigs

A dose of 30 mg ivermectin/kg b.w. (equal to 100 times the recommended dose) 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.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS FOR FISH AND AQUATIC LIFE.

Do not contaminate surface waters or ditches with this 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2021

15. OTHER INFORMATION

Pack sizes:

- Carton box with 1 glass vial of 50 ml
- Carton box with 1 glass vial of 100 ml

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.