

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Ivermectin: 10 mg

3. PACKAGE SIZE

50 ml
200 ml
250 ml
500 ml

4. TARGET SPECIES

Cattle, sheep and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal:

Cattle: 49 days.

Sheep: 42 days.
Pigs: 28 days.

Milk:

Do not use in lactating cows or ewes producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers or non-lactating dairy sheep within 60 days of calving/lambing.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

Protect from direct sunlight.

Keep the container in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

ECO Animal Health Europe Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 61471/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE or PET multidose container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Ivermectin: 10 mg

3. TARGET SPECIES

Cattle, sheep and pigs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

Subcutaneous use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal:

Cattle: 49 days.

Sheep: 42 days.

Pigs: 28 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Protect from direct sunlight.
Keep the container in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

ECO Animal Health Europe Limited

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ecomectin 10 mg/ml solution for injection for cattle, sheep and pigs.

2. Composition

Each ml contains:

Active substance:

Ivermectin: 10 mg

Excipients:

Benzyl alcohol: 10 mg

A clear, colourless solution.

3. Target species

Cattle, sheep and pigs.

4. Indications for use

Cattle:

For the treatment of gastrointestinal nematodes, lungworms, eyeworms, warble flies, mites and lice (as shown below) of beef and non-lactating dairy cattle:

Gastrointestinal worms (adults and 4th stage larvae):

Ostertagia ostertagi

Ostertagia lyrata

Haemonchus placei

Trichostrongylus colubriformis

Cooperia oncophora (adults)

Cooperia punctata (adults)

Cooperia pectinata (adults)

Bunostomum phlebotomum

Oesophagostomum radiatum

Lungworms (adult and 4th stage larvae):

Dictyocaulus viviparus

Eyeworms (adult):

Thelazia spp.

Warble flies (parasitic stages):

Hypoderma bovis

H. lineatum

Mites:

Psoroptes ovis

Sarcoptes scabiei var. *bovis*

Sucking lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

May also be used as an aid in the control of the mange mite *Chorioptes bovis* but complete elimination may not occur.

Treatment with the veterinary medicinal product at the recommended dose rate prevents re-infection with *Haemonchus placei*, *Cooperia oncophora*, *Cooperia pectinata* and *Trichostrongylus axei* for 7 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* for 14 days after treatment and *Dictyocaulus viviparus* for 21 days after treatment.

Sheep:

For the treatment of psoroptic mange (sheep scab), gastrointestinal nematodes, lungworms and nasal bots of sheep:

Gastrointestinal roundworms (adults):

Ostertagia circumcincta

Haemonchus contortus

Trichostrongylus axei

T. colubriformis and *T. vitrinus*

Cooperia curticei

Nematodirus filicollis

Variable activity may be observed against *Cooperia curticei* and *Nematodirus filicollis*.

Lungworms:

Dictyocaulus filaria (adults)

Mange mites:

Psoroptes ovis

Nasal bot:

Oestrus ovis (all larval stages)

Pigs:

For the treatment of gastro-intestinal nematodes, lungworms, lice and mange mites of pigs.

Gastro-intestinal worms (adult and 4th stage larvae):

Ascaris suum

Hyostrongylus rubidus

Oesophagostomum spp.

Strongyloides ransomi (adults).

Lungworms:

Metastrongylus spp. (adults)

Lice:

Haematopinus suis

Mange Mites:

Sarcoptes scabiei var. *suis*

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not administer by the intravenous or intramuscular route.

6. Special warnings

Special warnings:

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 veterinary medicinal 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.

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.

Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasite 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.

Resistance to ivermectin has been reported in *Ostertagia circumcincta* in lambs and in *Ostertagia ostertagi* in cattle. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of these *helminth species* and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:

Do not combine treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

The shedding of nematode eggs can continue for some time after treatment.

In Cattle: To avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites.

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: 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 immediately and show the package leaflet or the label to the physician.

Other precautions

Ivermectins may not be well tolerated in non-target species. Cases of intolerance with fatal results are reported in dogs – especially collies, old English sheepdogs and related breeds and crosses, and also in turtles/tortoises.

Pregnancy, lactation and fertility:

Can be used during pregnancy in cows, ewes and sows.

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.

Do not use in lactating ewes producing milk for human consumption. Do not use in sheep which are intended to produce milk for human consumption within 60 days of lambing.

The fertility of males is not affected by administration of the product.

Interaction with other medicinal products and other forms of interaction:

Do not combine ivermectin treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

Overdose:

Clinical symptoms of ivermectin toxicity include ataxia and depression. No antidote has been identified. In case of overdose, symptomatic treatment should be given. No signs of toxicity were observed in animals treated at up to 3 times the recommended dose rate.

Major incompatibilities:

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

7. Adverse events

Cattle, sheep and pigs:

Undetermined frequency (cannot be estimated from the available data):	Discomfort ^{1,2} , Injection site swelling ³ , Injection site thickening ³
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¹ Transitory immediately after subcutaneous administration.

² In cattle jumping and rolling may occur, but behaviour returns to normal after 15 minutes.

³ Transient and typically disappear within 1 to 4 weeks.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Subcutaneous use.

For single administration only (except for the treatment of *Psoroptes ovis* infections in sheep).

Cattle

Dosage:

1.0 ml per 50 kg bodyweight (based on a recommended dosage level of 200 micrograms ivermectin per kg bodyweight).

Administration:

Inject subcutaneously in front of, or behind, the shoulder using aseptic technique. A sterile 1.4 x 15 mm (17G x ½ inch) needle is recommended.

Sheep

Dosage:

0.5 ml per 25 kg of bodyweight (based on a recommended level of 200 micrograms ivermectin per kg bodyweight).

Administration:

For the treatment of gastrointestinal roundworms, lungworms and nasal bots inject once subcutaneously in the neck, using aseptic precautions; a sterile 1.4 x 15 mm (17G x ½ inch) needle is recommended. For the treatment of *Psoroptes ovis* (sheep scab), two injections with a seven-day interval are required to treat clinical signs of scab and to eliminate living mites.

For young lambs weighing less than 20.0 kg give 0.1 ml per 5 kg. In these lambs the use of a syringe which can deliver as little as 0.1 ml is recommended.

Pigs

Dosage:

1.5 ml per 50 kg bodyweight (based on a recommended dosage level of 300 micrograms ivermectin per kg bodyweight)

Administration:

The recommended route of administration is by subcutaneous injection into the neck using aseptic technique and a sterile 1.4 x 15 mm (17G x ½ inch) needle.

For piglets weighing less than 16 kg give 0.1 ml per 3 kg. In these piglets the use of a syringe which can deliver as little as 0.1 ml is recommended.

When using the 200, 250 or 500 ml pack sizes, use only automatic syringe equipment. For the 50 ml pack size, use of a multiple dose syringe is recommended. To refill the syringe, use of a draw-off needle is recommended to avoid excessive broaching of the stopper.

9. Advice on correct administration

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. Accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over-dosing.

10. Withdrawal periods

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: 42 days.

Do not use in lactating ewes producing milk for human consumption. Do not use in sheep which are intended to produce milk for human consumption within 60 days of lambing.

Pigs:

Meat and offal: 28 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25 °C.

Protect from direct sunlight.

Keep the container in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and 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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product or used container should not enter water courses as ivermectin may be EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 61471/3000

Pack sizes: Cardboard box with 1 vial of 50 ml, 200 ml, 250 ml and 500 ml.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Eco Animal Health Europe Limited
6th Floor
South Bank House
Barrow Street
Dublin 4
D04 TR29
Ireland

Manufacturer responsible for batch release:

Divasa-Farmavic, S.A.
Ctra. Sant Hipòlit, km 71,
08503 Gurb-Vic (Barcelona)
SPAIN

Or

Produlab Pharma b.v
Forellenweg 16, NL-4941, Sj Raamsdonksveer
Netherlands

Local representatives and contact details to report suspected adverse events:

Gavin Hall
Approved: 22 April 2026