B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bimectin vet. 10 mg/ml Solution for Injection

2. Composition

1 ml contains:

Active substance:

Ivermectin 10 mg

Clear colourless to slightly yellow coloured solution.

3. Target species

Cattle, reindeer and pigs.

4. Indications for use

Ivermectin is active against several invertebrates, such as roundworms, parasitic stages of warbles, mange mites and lice.
Due to the ivermectin the parasites are paralyzed and killed.
Cattle:
Gastro-intestinal roundworms (adult and fourth stage larvae, L4)
Ostertagia ostertagi. (including inhibited L4)
Ostertagia lyrata
Haemonochus placei
Trichostrongylus axei
Trichostrongylus colubriformis (L4)
Cooperia spp.
Oesophagostomum radiatum
Nematodirus spathiger (adult)

Lungworms (adult and fourth stage larvae, L4)
Dictyocaulus viviparus.

Warbles (larval stages)
Hypoderma bovis
Hypoderma lineatum

Mange mites
Sarcoptes scabiei var. bovis
Psoroptes bovis

Lice
Linognathus vituli
Haematopinus eurysternus

Reindeer:
Warbles (larval stages)

Hypoderma tarandi

Pigs:
Gastro-intestinal roundworms (adult and fourth stage larvae, L4)
Ascaris suum
Hyostrongylus rubidus
Oesophagostomum spp.
Strongyloides ransomi (adult)

Lungworms
Metastrongylus spp. (adult)

Mange mites
Sarcoptes scabiei var. *suis*

Lice
Haematopinus suis

5. Contraindications

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

6. Special warnings

Special warnings:
Unnecessary use of antiparasitics or use deviating from the instructions given in the product information may increase the risk of resistance development and lead to reduced efficacy.

Guidance for each specific animal or herd should be sought from the responsible veterinarian.

Special precautions for safe use in the target species:
Newborn piglets are sensitive to ivermectin overdose. This is probably due to the fact that the blood-brain barrier during the newborn period is more permeable to ivermectin. Therefore, the product should not be given to piglets under 5 days old.

This veterinary medicinal product could be harmful for other species than cattle, reindeer and swine. (Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

Special precautions for the protection of the environment:
See the 'Special precautions for disposal' section of this package leaflet.

Pregnancy and lactation:
The veterinary medicinal product can be administered to beef cows and pigs at any stage of pregnancy or lactation. The veterinary medicinal product should not be given to lactating cows or heifers and dry cows within 60 days prior to calving, when the milk is intended for human consumption.

Overdose:
Severe overdose (4-30 mg/kg) can lead to lethargy, poor muscle control and coordination and tremor.

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, reindeer and pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site reaction*

*Local reaction at the injection site may occur.

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Subcutaneous use.

Cattle and reindeer: 1 ml per 50 kg bodyweight, corresponding to 0.2 mg ivermectin per kg bodyweight.

Pigs: 1 ml per 33 kg bodyweight, corresponding to 0.3 mg ivermectin per kg bodyweight.

9. Advice on correct administration

Please note that your veterinarian could have prescribed this veterinary pharmaceutical for a different usage and/or in a different dosage than given in this information. You should always follow the veterinary prescription and the directions on the label from the pharmacy.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogenous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

10. Withdrawal periods

Meat and offal:
Cattle: 49 days
Reindeer and pigs: 28 days

Not authorised for use in lactating cows producing milk for human consumption.
Do not use in pregnant dry cows and heifers which are intended to produce milk for human consumption within 60 days of expected calving.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the vial 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 should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

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. These measures should help to protect the environment.

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

Packaging sizes:
Cardboard box with 1 x 50 ml plastic vial.
Cardboard box with 1 x 250 ml plastic vial
Cardboard box with 6 x 250 ml plastic vials
Cardboard box with 1 x 500 ml plastic vial

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

2023-10-18

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Tallaght
Dublin 24
Ireland

Local representatives and contact details to report suspected adverse reactions:

17. Other information