Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
Veterinary medicine package leaflet
This medicine is dispensed with a veterinarian's prescription only
For use in animals only

1) Name, form and strength of the veterinary medicine:

Ivomec veterinary
Solution for subcutaneous injection

2) Name of active ingredient and its concentration in a unit dose:

Ivermectin 10 mg/ml

For a list of inactive ingredients and allergens in this medicine, see section 13.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your veterinarian or pharmacist.

3) What is this medicine intended for?

This medicine is intended for treating cattle and sheep external and internal parasites.

Cattle: To treat the following parasites:

Type of cattle parasite	Adult	L4	Inhibited L4
Gastrointestinal roundworms:			
Ostertagia lyrate	•	•	
Ostertagia ostertagi	•	•	•
Cooperia oncophora	•	•	
Cooperia pectinata	•	•	
Cooperia punctata	•	•	
Haemonchus placei	•	•	
Trichostrongylus axei	•	•	
Trichostrongylus colubriformis	•	•	
Bunostomum phlebotomum	•	•	
Oesophagostomum radiatum	•	•	
Strongyloides papillosus	•		
Nematodirus helvetianus	•		
Nematodirus spathiger	•		
Trichuris spp.	•		
Lungworms:			
Dictyocaulus viviparus	•	•	
Eyeworms:			
Thelazia spp	•		

Warbles: *Hypoderma bovis H. lineatum*
Mange mites: *Psoroptes ovis; Sarcoptes scabei var. bovis*
Sucking lice: *Linognathus vituli; Haematopinus eurysternus; Solenopotes capillatus*

The product may also be used to control biting lice (*Damalinia bovis*) and the mange mite *Chorioptes bovis*, although treatment may not eliminate them completely.

Persistent infections: Given at the recommended dosage of 1 ml per 50 kg animal bodyweight, the product prevents re-infection with the following nematodes for the following durations:

Parasite	Number of days after treatment
Barbers pole worm – *Haemonchus placei*	14
Small intestinal worm – *Cooperia* spp.	14
Hairworm – *Trichostrongylus axei*	14
Brown stomach worm – *Ostertagia ostertagi*	21
Nodular worm – *Oesophagostomum radiatum*	21
Lungworm – *Dictyocaulus viviparus*	28

The timing of treatment should be based on local epidemiological factors and should be adapted for each individual farm. The veterinarian will determine the dosage.

Sheep: To treat the following parasites:

Type of sheep parasite	Adult	L4	Inhibited L4
Gastrointestinal roundworms:			
Ostertagia circumcincta	•	•	•
O. trifurcata	•	•	
Haemonchus contortus	•	•	•
Trichostrongylus axei	•		
T. colubriformis	•	•	
T. vitrinus	•		
Cooperia curticei	•	•	
Oesophagostomum columbianum	•	•	
O. venulosum	•		
Nematodirus filicollis	•	•	
Chabertia ovina	•	•	
Trichuris ovis	•		
Lungworms:			
Dictyocaulus filaria	•	•	
Protostrongylus rufescens	•		
Nasal bots:			
Oestrus ovis			
Mange mites:			
*Psoroptes ovis**			
Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are eliminated by this product.			

Therapeutic group: This medicine is a systemic (internal) antiparasitic.

4) Contraindications

Do not use this medicine if:
- Do not inject intravenously or intramuscularly.
- If the animal is sensitive (allergic) to the active ingredient, to macrocyclic lactones (the active ingredient is a member of this group of substances) or to any of the other ingredients in this medicine. The active ingredient is listed in section 2 and the other ingredients are listed in section 13.
- The product is specifically for use in the indicated species (cattle and sheep). Do not use in other species as side effects reactions, including fatalities may occur (in dogs for example).

5) Side effects

Like with all medicines, using this medicine may cause side effects in some users. Do not be alarmed by this list of side effects; the animal may not experience any of them.

Side effects in 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. These reactions usually disappeared without treatment within a short time.

Side effects in sheep: Discomfort, sometimes intense but usually transient, has been observed in sheep following subcutaneous administration. These reactions usually disappeared without treatment within a short time.

If any side effect gets worse, or if an animal experiences a side effect not mentioned in this leaflet, consult your veterinarian.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

6) Target species

This medicine is intended for use in cattle and sheep only.

7) Dosage and method of administration

Always use as instructed by your veterinarian. Check with the veterinarian or pharmacist if you are not sure. Only the veterinarian will determine the dose, and how to administer this treatment.
Do not exceed the recommended dose.

Route of administration: Solution for subcutaneous injection only.

Dosage: 200 microgram ivermectin per kg animal bodyweight.
Every 1 ml of solution contains 10 mg invermectin which is sufficient for 50 kg animal bodyweight.

Use the following table to work out the required dose:

Cattle (1 ml of solution sufficient for 50 kg animal bodyweight)			
Bodyweight (kg)	Dose volume (ml)	Body weight (kg)	Dose volume (ml)
Up to 50 kg	1.0 ml	201 to 250 kg	5.0 ml
51 to 100 kg	2.0 ml	251 to 300 kg	6.0 ml
101 to 150 kg	3.0 ml	301 to 350 kg	7.0 ml
151 to 200 kg	4.0 ml	351 to 400 kg	8.0 ml

For cattle weighing over 400 kg, calculate the dose at the rate of 1 ml per 50 kg animal bodyweight.

Sheep (0.5 ml of solution sufficient for 25 kg animal bodyweight)			
Bodyweight (kg)	Dose volume (ml)	Body weight (kg)	Dose volume (ml)
Up to 5 kg	0.1 ml	25.1 to 50 kg	1.0 ml
5.1 to 10 kg	0.2 ml	50.1 to 75 kg	1.5 ml
10.1 to 15 kg	0.3 ml	75.1 to 100 kg	2.0 ml
15.1 to 25 kg	0.5 ml		

For sheep weighing over 100 kg calculate the dose at the rate of 0.5 ml per 25 kg animal bodyweight.

This medicine can be used in cattle and sheep of any age.

Frequency of administration: When treating sheep scab/mange mites administer two injections 7 days apart. A single injection may improve the animal's condition but will not eliminate the problem.

Do not administer this medicine in the dark! Check the label and the dose every time you administer medicine to an animal. Wear glasses if you need them. If you have any further questions about using this medicine, consult your veterinarian or pharmacist.

8) How to use this medicine:

- Use a sterile standard automatic or disposable syringe with a hypodermic needle.
- Use of a sterile 17-gauge 13 mm needle is suggested. Use sterile syringe and needles. Replace with a fresh sterile needle after every 10 to 12 animals.
- Disinfect the bottle stopper before inserting the needle through it.
- Injecting wet or dirty animals is not recommended.
- Cattle: Inject under the skin in front of, or behind, the shoulder.
- Sheep: Inject under the skin in the neck.
- With sheep smaller than 16 kg, use of a 1 ml syringe with 0.1 ml increments is suggested.
- If treating an individual sheep, use of a syringe not exceeding 2.0 ml with increments of 0.1ml is suggested.

9) Withdrawal period

Withdrawal periods before slaughter:
Cattle (meat and offal): Do not treat cattle for 49 days before slaughter.
Cattle (dairy): 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.
Sheep (meat and offal): Do not treat sheep for 42 days before slaughter.
Sheep (dairy): Do not use in sheep producing milk for human consumption.

10) Warnings

- **Special warnings about treating the target animal with this medicine:** To prevent the development of parasite resistance to this medicine which makes treatment ineffective, avoid: too frequent use of ivermectin and substances from the same therapeutic group (see section 3); underdosing, which may be due to underestimation of bodyweight; incorrect administration of the product, or incorrect calibration of the dosing device.
- **Special warnings about the safety of using this medicine in animals:** When treating groups of animals only use an automatic dosing device. Withdraw solution from the bottle with the syringe attached a sterile dry needle that is used to withdraw solution from bottles. Bottle stoppers must not be broached more than 20 times. Sheep scab (mange mites) is an extremely contagious disease. Ensure there is no re–infestation, as mites can survive for up to 15 days without the sheep. Therefore it is important that all sheep which have been in contact with infected sheep are treated as well. Prevent contact between treated and untreated flocks for at least seven days after treatment.
- **Special safety precautions for the person administering the medicine** Do not smoke, drink, or eat while handling the medicine. Avoid accidentally injecting yourself and others: In people, an injection may cause local irritation and/or pain at the site of injection. Wash hands after using the medicine.
  If you have accidentally injected a person or if a person has swallowed some medicine (particularly if it is a child), immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
- **Pregnancy and lactation:** This product can be administered to pregnant and lactating cows and ewes (except cows during the 60 days before calving) provided that the milk is not used for human consumption. It can be administered to breeding cattle and sheep without affecting fertility.
- **Drug interactions and other interactions:** No adverse reactions were observed when this medicine was given alongside foot and mouth disease vaccine or clostridial vaccine, at separate injection sites.
  Adequate vaccination of sheep against clostridial infections is recommended.
- **Overdose:** An overdose of 20 times more than recommended (i.e. a single dose of 4.0 mg ivermectin per kg animal weight), given subcutaneously, resulted in ataxia and depression. No antidote has been identified. Supportive care may be beneficial.
- **Incompatibility:** As there is no information, do not mix this medicinal product with other veterinary medicinal products.

11) Storage instructions

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions** Store below 25°C. Protect from light.
- **Shelf-life after first opening:** Use immediately after opening and destroy any remaining medicine. Can be used in more than one animal.

12) Instructions for the disposal of unused product or waste materials

- Do not throw away any medicines in the toilet or in household waste. Dispose of any remaining veterinary medicine or waste from using a veterinary medicine in the same manner as toxic waste; do not discard in wastewater.
- Ask your pharmacist or veterinarian how to dispose of medicines that have expired or that you no longer use. These measures will help protect the environment.

13) Additional information

- **In addition to the active ingredients, this medicine also contains the following inactive ingredients:**
  glycerol formal and propylene glycol.
  This product does not contain a preservative.
- **What the medicine looks like and contents of the pack:** This medicine is a clear pale yellow (straw-colored) solution.
- It is packaged in a plastic bottle with a rubber stopper and sealed with an aluminum cap over the stopper. Bottles are packed in cartons.
- **Pack size:** This medicine is supplied in bottles of 50 or 500 ml. Each carton contains one bottle.
- Not all pack sizes may be marketed.
- **Registration holder:** Beit Erez Havat Milatin Ltd., POB 209, Mishmar Hashiva 5029700.
- **Manufacturer:** Boehringer Ingelheim Animal Health France, Lyon, France (by Boehringer Ingelheim Animal Health do Brazil, Sao Paolo, Brazil, and Boehringer Ingelheim Animal Health France, Toulouse, France).

Registration number of the medicine in the Ministry of Health's National Drug Registry: 082-16-91443-00

This medicine is intended for cattle and sheep.

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