The following text is currently approved by the National Organization for Medicines (E.O.F.) in Greece and is subject to changes at any time.

PACKAGE LEAFLET

For animal treatment only

VETERMEC

injectable solution of ivermectin for cattle, pigs, sheep, goats

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

Marketing Authorisation Holder:
PROVET S.A.
120 Eleftherias Avenue, Eleousa, Zitsa, 45500 Ioannina, Greece
Tel.: +30 2105508500, +30 2105575770-3
E-mail: vet@provet.gr

Manufacturer responsible for batch release:
PROVET S.A. (FACTORY)
Nikiforou Foka & Ag.Anargyron, Thesi Vrago,
193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETERMEC
injectable solution
10 mg/ml, Ivermectin,
for cattle, pigs, sheep, goats

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml of solution contains:
Active substance: 10 mg Ivermectin
Excipients: Glycerol formal, Propylene glycol

4. INDICATIONS

VETERMEC injectable solution is recommended cases, such as infestation of pigs, sheep and cattle caused by gastrointestinal nematodes and lungworms and certain skin ectoparasites. It is also effective against renal parasites of pigs.
When administered subcutaneously, at the recommended doses, it is effective against the following parasites:

Cattle

Gastrointestinal nematodes: *Ostertagia* spp. (adult and larvae of fourth stage including sub biotic stages of *O. ostertagi*), *Haemonchus placei* (adult and larvae of fourth stage), *Trichostrongylus axei* (adult and larvae of fourth stage), *Cooperia* spp. (adult and larvae of fourth stage), *Oesophagostomum radiatum* (adult and larvae of fourth stage), *Nematodirus helvetianus* (adult), *Bunostomum phlebotomum* (adult and larvae of fourth stage), *Toxocara* (*Neoscaris*) *vitulorum* (adult)
Lungworms: *Dictyocaulus viviparous* (adult, larvae of fourth stage and sub biotic stages)
Other nematodes**:** *Parafilaria bovicola* (adult), *Thelazia* spp. (adult)
Warbles: *Hypoderma bovis* (parasitic larvae stages), *Hypoderma lineatum*
Lice: *Linognathus vituli, Haematopinus eurysternus, Solenoptes capillatus* (assisting the control of *Damalinia bovis*)
Acari: *Psoroptes ovis* (*communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis* (assisting the control of *Chorioptes bovis*)
Tics**:** *Ornithodoros savignyi*

Pigs

Gastrointestinal nematodes (adult and larvae of fourth stage): *Ascaris suum*, *Hyostrongylus rubidus* (adult and larvae of fourth stage), *Oesophagostomum* spp. (adult and larvae of fourth stage), *Trichuris suis* (adult), *Strongyloides ransomi* (adult)

VETERMEC injectable solution is administered to sows 7-14 days before farrowing. Thus, effectively prevents the transmission of *Strongyloides ransomi* through the milk to the piglets.
Lungworms (adult stages): *Metastrongylus* spp.
Renal parasites **(**adult stages and L_4): *Stephanurus dentatus*
Lice**:** *Haematopinus suis*
Acari: *Sarcoptes scabiei* var. *suis*
As the ivermectin is not directly effective against acari, caution is required in order to prevent the transmission of the infection to the non-treated animals. Generally, treated animals should not be relocated to clean areas and not come into contact with non-infected pigs for at least 1 week after the end of the treatment. The eggs of lice are not affected by the administration of ivermectin and a period of up to 3 weeks may be required for hatching.

Sheep-Goats
Gastrointestinal nematodes: *Haemonchus contortus* (adult nematodes and L_4 and L_3 larvae), *Ostertagia circumcincta* (adult nematodes and L_4 and L_3 larvae), *O. trifurcata* (adult nematodes and L_4 larvae), *Trichostrongylus axei* (adult nematodes), *T. colubriformis* (adult nematodes and L_4 and L_3 larvae), *T. vitrinus* (adult nematodes), *Nematodirus filicollis* (adult nematodes and L_4 larvae), *Nematodirus spathiger* (L_4 and L_3), *Cooperia curticei* (adult nematodes and L_4 larvae), *Oesophagostomum columbianun* (adult nematodes and L_4 and L_3 larvae), *O. venulosum* (adult nematodes), *Chabertia ovina* (adult nematodes and L_4 larvae), *Trichuris ovis* (adult nematodes), *Strongyloides papillosus* (L_4 and L_3), *Gaygeria pachyscelis* (adult nematodes and L_4 and L_3)
Lungworms: *Dictyocaulus filaria* (adult nematodes and L_4 and L_3 larvae), *Protostrongylus rufescens* (adult nematodes)
Nasal bots (all larvae stages)**:** *Oestrus ovis*
Acari: *Sarcoptes scabiei*, *Psoroptes communis* var. *ovis*, *Psorergates ovis*
One injection dramatically reduces the population of *P. communis* var. *ovis* and often resolves the clinical symptoms of mange.
In order for acari to disappear, two injections are required in a period of 7 days.

5. CONTRAINDICATIONS
Do not administer intravenously or intramuscularly.

6. ADVERSE REACTIONS
In some cattle transient pain may be observed following subcutaneous injection.
Oedema of the soft tissues at the site of injection has been recorded, which resolves without specific treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

7. TARGET SPECIES
Cattle, Pigs, Sheep, Goats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Cattle: Administer subcutaneously in front of or behind the shoulder 1 ml VETERMEC injectable solution, for every 50 kg of b.w. (200 μg active substance/ kg of b.w.) with a single subcutaneous injection.
Pigs: Administer subcutaneously at the neck 1 ml VETERMEC injectable solution, for every 33 kg of b.w. (300 μg active substance/ kg of b.w.) with a single subcutaneous injection.

Sheep, goats: Administer subcutaneously behind the shoulder 0.5 ml VETERMEC injectable solution, for every 25 kg of b.w. (200 μg active substance/ kg of b.w.) with a single subcutaneous injection.
For the treatment of *Psoroptes ovis* is required two doses, which are injected in two different sites at the maximum recommended dose in a period of 7 days.

- When to treat for *Hypoderma*
Injectable ivermectin is very effective against all stages of *Hypoderma* of cattle. However, it is important to treat at the right time. For best results, treat immediately after the end of the period of the adult fly (when loss of viability is seen). The destruction of the *Hypoderma* larvae during the period that these are found in vital areas of the body may cause adverse allergic reactions to the host. The destruction of *Hypoderma lineatum* larvae found in the spinal cord may cause paresis or paralysis. This is not related to the activity of ivermectin itself, but rather to the mass release of antigens seen during the death of 2nd and 3rd stage larvae. Thus, this can take place regardless of the type of drug used for the treatment of *Hypoderma*. Cattle should be treated before these larval stages. Cattle treated with ivermectin after the period of the fly can be treated again with ivermectin during the winter for endoparasites, acari or lice without the danger of adverse reactions related to *Hypoderma.*
The application of a proper therapeutic program is recommended.

- Recommended treatment schemes for pigs
Breeding animals-it is important to treat all animals in the herd with ivermectin at the initiation of any parasite control program. Thereafter, use ivermectin regularly as follows:
Sows-Gilts: Treat preferably 7-14 days prior to breeding, as to minimize the possibility of infection of piglets. Also administer 7-14 days prior to parturition.
Boars: Treat at least twice a year depending on the severity of the condition.
Fattening pigs: All animals should be treated before been placed in clean quarters and when endo and ecto parasites are present.

9. ADVICE ON CORRECT ADMINISTRATION
Cattle: The recommended route of administration is via subcutaneous injection. The loose skin in front or behind the shoulder is an acceptable spot. The use of a sterile needle 16G and 15-20 mm length is recommended.
Pigs: The recommended route of administration is via subcutaneous injection at the dorsal area of the neck. The solution can be administered with any syringe, automated or single dose, aseptically.
Sheep-Goats**:** The recommended route of administration is via subcutaneous injection. The solution can be administered with any syringe, automated or single dose, aseptically. The loose skin behind the shoulder is an acceptable spot. In sheep with thick puck of hair, make sure that the needle has penetrated the hair and the skin before administering the dose.

10. WITHDRAWAL PERIODS
Cattle: Meat and edible tissues: 49 days
Do not administer to dairy cows, whose milk is intended for human consumption. Do not administer to non-lactating cows as well as to pregnant heifers the last 60 days prior to parturition.
Pigs: Meat and edible tissues: 28 days
Sheep: Meat and edible tissues: 39 days
Do not administer to sheep, whose milk is intended for human consumption. Do not administer to sheep the last 60 days prior to parturition when the milk is intended for human consumption.
Goats: Meat and edible tissues: 59 days
Do not administer to goats, whose milk is intended for human consumption. Do not administer to goats the last 60 days prior to parturition when the milk is intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Store below 25 °C
Protect from light.
Shelf-life after the first opening according to instructions: 20 days

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

12. SPECIAL WARNINGS

Special warnings for each target species

Do not administer to animals during milk production or 60 days before farrowing in cattle and sheep.

Special precautions for use in animals:

Administer subcutaneously at the recommended dosage.

Doses larger than 10 ml should be administered in two injection sites in order to minimize the pain and local irritation.

Use different sites of injection for the administration of other parenteric preparations.

Accuracy in dosing is important in young piglets, especially for those weighting less than 16 kg and when the dose of ivermectin is smaller than 0.5 ml. The use of syringe with 0.1 ml sub degrees is recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not smoke or eat during administration.

Wash hands after use.

Lactation, Pregnancy:

Do not administer to animals during milk production or 60 days before farrowing in cattle, sheep and goats.

Interaction with other medicinal products and other forms of interaction:

None known

Overdose (symptoms, emergency procedures, antidotes):

No antidote has been found. Nevertheless, symptomatic treatment can help the animal.

Cattle: Administration of a single 4.0 mg ivermectin/ kg dose (20 times the recommended dosage) subcutaneously resulted in ataxia and depression.

Pigs: Administration of 30 mg ivermectin/ kg dose (100 times the recommended dose of 0.3 mg/ kg) subcutaneously in pigs resulted in lethargy, ataxia, bilateral mydriasis, intermittent tremor, difficulty in breathing and lateral decumbency.

Sheep: Administration of a total 4.0 mg ivermectin/ kg dose (20 times the recommended dosage) subcutaneously resulted in ataxia and depression.

Incompatibilities:

Ivermectin has been administered concurrently with rafoxanide and the vaccine of enterotoxemia without causing an adverse reaction. Other injectable products should be administered at a different location.

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

Studies indicate that, when ivermectin comes in contact with the soil is linked with it and stays inactivated for a long period of time. Vials and remains of the drug must be securely destroyed (incineration). These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MAY 2013

15. OTHER INFORMATION

PACKAGES

Vial of 15 ml, 50 ml and 100 ml

Not all packages may be marketed.

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

under veterinary medical prescription

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN