PACKAGE LEAFLET

AFILARIA SR 3.4 mg/ml powder and solvent for suspension for injection for dogs (EL, FR, PT, SI).
AFILARIA liberación prolongada 3.4 mg/ml powder and solvent for suspension for injection for dogs (ES).
PREVENGO SR 3.4 mg/ml powder and solvent for suspension for injection for dogs (IT).

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

FATRO S.p.A. - Via Emilia, 285 - Ozzano dell'Emilia (BO), Italy.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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AFILARIA liberación prolongada 3.4 mg/ml powder and solvent for suspension for injection for dogs (ES).
PREVENGO SR 3.4 mg/ml powder and solvent for suspension for injection for dogs (IT).
Moxidectin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Each gram of powder (microspheres) contains:

Active substance:		
Moxidectin	100	mg

Excipients, q.s.

Each ml of solvent contains:

Excipients:		
Methyl parahydroxybenzoate (E218)	1.89	mg
Propyl parahydroxybenzoate	0.22	mg

Each ml of the reconstituted suspension contains:

Active substance:		
Moxidectin	3.4	mg
Excipients:		
Methyl parahydroxybenzoate (E218)	1.82	mg
Propyl parahydroxybenzoate	0.21	mg

Microspheres: white to pale yellow free flowing microspheres.
Solvent: clear to slightly opalescent, colourless to pale yellow solution.
Reconstituted suspension: homogeneous suspension without agglomerates.

4. INDICATIONS

For the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immittis*).
For the prevention of cutaneous lesions and of dermatitis caused by *Dirofilaria repens* (L3 larvae).

For the treatment of larval and adult infections of *Ancylostomum caninum* and *Uncinaria stenocephala* present at the time of treatment.
When administered within 1 month from the beginning of the activity of intermediate host (mosquitos), the product has demonstrated persistent efficacy for the whole duration of the risk of infection season for the heartworm disease caused by *D. immittis* and for cutaneous lesions caused by *D. repens* in Europe.
A persistent activity was not determined against *Ancylostomum caninum* and *Uncinaria stenocephala.*

5. CONTRAINDICATIONS

Do not use in dogs younger than 12 weeks of age.
Do not administer intravenously.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

In rare cases, there may be short-lived pain at the injection site or a slight moderate local reaction (swelling) for 2-3 weeks.
Granulomatous lesions, usually well-defined and of small dimension, were commonly found in the animals treated with the recommended dose. The average severity of lesions was registered as "modest".
In rare occasions, it is possible to observe local hypersensitivity reactions (i.e. face, mucosae, legs, testis, eyelids, lips) or generalized angioedema, urticaria, hitching or anaphylaxis.
Rarely diarrhoea, vomit, transient ataxia, tremors or lethargy were reported.
The product has demonstrated to be very safe even for species sensitive to ivermectins and animals resulted positive to test for heartworm disease.

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

Dogs.

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

To be administered subcutaneously at the dose of 0.17 mg of moxidectin/kg b.w. as a single injection, equivalent to 0.05 ml/kg b.w. of the final suspension of the reconstituted product.
For growing dogs between 12 weeks and 9 months of age, it is recommended to administer the complete dose of the reconstituted product considering the body weight at the moment of the treatment. Do not overdose in prevision of the final weight of the animal. Because of the rapid changing of body weight expected for 12-weeks puppies, a further treatment may be required to ensure complete efficacy. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

The treatment schedule should be based on veterinary diagnosis and on the local epidemiological situation.

For a purely indicative description, a dosage table is shown below:

Dog's body weight (kg)	Dose volume (mL)	Dog's body weight (kg)	Dose volume (mL)
1	0.05	35	1.75
5	0.25	40	2.00
10	0.50	45	2.25
15	0.75	50	2.50
20	1.00	55	2.75
25	1.25	60	3.00
30	1.50	65	3.25

For dogs over 65 kg, administer 0.25 mL every 5 kg b.w.

If the product is administered instead of another preventive monthly treatment, the dose must be administered within a month from the last administration.

Instruction for the preparation and administration of the product:

1. Withdraw all the vehicle contained in the solvent vial. Do not use any other solvent.
2. Slowly transfer all reconstitution fluid to the powder vial containing the moxidectin microspheres. In order to facilitate the transfer operation, it is recommended to use the adapter supplied in the package as described in the operating instructions. The adapter can be retained on the vial containing the reconstituted suspension and also used for subsequent pickup operations.
3. After adding all the reconstitution liquid into the vial of the microspheres, shake vigorously until all microspheres are suspended.
4. Leave the suspension for about 10 minutes or until all the larger bubbles have dissolved.
5. Take the appropriate dose with a syringe and treat the animal as soon as possible. In case of long wait before administration, the product may separate. In these cases, it is advisable to rotate the syringe gently to resuspend the product.
6. Before each treatment, the vial containing the reconstituted suspension should be softly overturned to resuspend the floating microspheres.
7. Always use caliber and size needles appropriate to the size of the animal. We recommend a 20G needle for animals weighing less than 20 kg and a 18G needle for those of higher weight.
8. For the expiration date, write the date of reconstitution of the product on the appropriate space on the box and on the label.

The vial with reconstituted product may be broached up to 34 times.
The syringes and needles supplied with the medicinal product should only be used for the preparation of the reconstituted suspension and must not be used for administering the reconstituted suspension to the animals.

9. ADVICE ON CORRECT ADMINISTRATION

The product must be used only in controlled dogs which were negative at the test for heartworm disease. Before starting the prophylactic treatment with the product, infected dogs must be treated to remove adult heartworms and microfilariae. These treatments must be performed under the Veterinary Surgeon's responsibility.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not freeze.
Keep the vials in the outer carton in order to protect from light.
After reconstitution store in a refrigerator (2 °C – 8 °C).
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 3 months.

After product reconstitution, the exact date for discarding the unused product should be calculated on the in-use shelf-life specified on this package leaflet. This discarding date should be written in the space provided on the outer carton and label.

12. SPECIAL WARNINGS

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).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests. 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.

Special precaution for use in animals:
The product must be used only in controlled dogs which were negative at the test for heartworm disease. Before starting the prophylactic treatment with the product, infected dogs must be treated to remove adult heartworms and microfilariae. These treatments must be performed under the Veterinary Surgeon's responsibility.

Special precautions to be taken by person administering the veterinary medicinal product to animals:
Moxidectin and esters of parahydroxybenzoic acid may cause allergic reactions. People with known hypersensitivity to moxidectin or to any of the excipients should avoid contact with the veterinary medicinal product.
Avoid contact with skin or eyes. Wash hands thoroughly after use. In case of accidental spillage onto skin, wash off immediately with soap and water. If the product accidentally gets into eyes, they should be thoroughly flushed with water.
Pay attention to avoid self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.
Advice to physician in case of accidental self injection: Treat symptomatically.

Use during pregnancy, lactation or lay
The safety of injectable moxidectin was established in pregnant bitches.

Interaction with other medicinal products and other forms of interaction
The effects of GABA agonists are increased by moxidectin.

Overdose
In the majority of subjects treated with a dose equal or higher than 0.5 mg/kg b.w. (3-fold or more the recommended dose), granulomatous lesions are observed with a moderate severity.

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

Environmental properties
Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance.

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

Medicines should not be disposed via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package size:
1 powder vial of 592 mg + 1 solvent vial of 17 ml + adapter
1 powder vial of 592 mg + 1 solvent vial of 17 ml + adapter + syringe + needle
1 powder vial of 197.3 mg + 1 solvent vial of 5.67 ml + adapter
1 powder vial of 197.3 mg + 1 solvent vial of 5.67 ml + adapter + syringe + needle

INSTRUCTION FOR THE USE OF THE ADAPTER

In order to allow a functional and effective transfer of the solvent into the vial with the microspheres by a practical and effective way, it is advisable to use the Adapter supplied within the package. Thanks to its hermetic closure that maintains sterility, the Adapter allows multiple drawings of the product with maximum functionality.

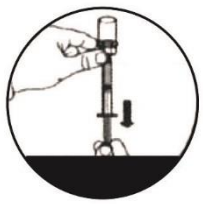
Do not use if the package is damaged. Do not pierce the valve.

Remove the protective film from the adapter pack without pulling it out. Remove the Flip-Off closure from the vial of the microspheres and position the Adapter using the package in which it is contained, avoiding direct contact with your hands. Insert the Adapter into the vial by pushing it vertically down until it has completely penetrated into the rubber stopper of the vial.

Remove the Flip-Off Closure from the solvent vial and withdraw with a syringe (recommended with luer lock system) all the liquid contained in the vial. Insert the solvent-filled syringe without the needle on the adapter.

Slowly transfer the solvent into the vial with microspheres. Do this carefully, paying attention to the air contained in the vial and that the solvent will not spill.

Once all the reconstitution liquid has been added to the vial with microspheres, remove the syringe from the Adapter and vigorously shake the vial until all microspheres are suspended.



The Adapter can be left on the reconstituted product vial.
To withdraw the suspension with microspheres, insert a new needle-free syringe and, holding the vial overturned, withdraw the amount of reconstituted suspension needed for the treatment. For proper administration read the package leaflet. Do not hold the vial overturned in the refrigerator when the Adapter is engaged.