[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Afilaria SR 3.4 mg/ml powder and solvent for suspension for injection for dogs (AT, BG, CZ, EL, FR, HR, HU, PT, RO, SI, SK)

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)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of powder of 197.3 mg of microspheres contains:

Active substance:
Moxidectin 19.73 mg

Each vial of powder of 592 mg of microspheres contains:

Active substance:
Moxidectin 59.2 mg

Excipients:

Qualitative composition of excipients and other constituents
Powder (microspheres)
Cholesterol
Carnauba wax (E903)
Hydrogenated palm oil
Glyceryl tristearate

Each vial of solvent (5.67 ml or 17 ml) contains:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Solvent	
Methyl parahydroxybenzoate (E218)	1.89 mg/ml
Propyl parahydroxybenzoate	0.22 mg/ml
Sodium chloride	
Hypromellose 2910 (E464)	
Hydrochloric acid, dilute (for pH adjustment)	
Water for injections	

Each ml of the reconstituted suspension contains:

Active substance:
Moxidectin 3.4 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E218)	1.82 mg/ml
Propyl parahydroxybenzoate	0.21 mg/ml
Cholesterol	
Carnauba wax (E903)	
Hydrogenated palm oil	
Glyceryl tristearate	
Sodium chloride	
Hypromellose 2910 (E464)	
Hydrochloric acid, dilute (for pH adjustment)	
Water for injections	

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

3. CLINICAL INFORMATION

3.1. Target species

Dogs.

3.2. Indications for use for each target species

For the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*).
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 veterinary medicinal product has demonstrated persistent efficacy for the whole duration of the risk of infection season for the heartworm disease caused by *D. immitis* and for cutaneous lesions caused by *D. repens* in Europe.
A persistent activity was not determined against *Ancylostomum caninum* and *Uncinaria stenocephala.*

3.3. 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.

3.4. 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 body weight, 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. 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.

3.5. Special precautions for use

Special precautions for safe use in the target species:

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

The veterinary medicinal product has demonstrated to be very safe even for species sensitive to ivermectins and animals resulted positive to test for heartworm disease.

Special precautions to be taken by the 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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Injection site granuloma [1]. Injection site pain[2], Injection site swelling[2].
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reaction[3], Angioedema, Urticaria, Anaphylaxis[4]; Itching; Lethargy.Anorexia[5]
Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea, Vomiting; Ataxia[6], Tremor.

[1] Usually well-defined and of small dimension, the average severity of lesions was registered as "modest".
[2] Short-lived pain at the injection site or a slight moderate local reaction (swelling) for 2-3 weeks.
[3] Possible local reactions (i.e. face, mucosae, legs, testis, eyelids, lips).
[4] If such reaction occurs, appropriate treatment should be administered without delay.
[5] It is reasonable to assume that it was a consequence of the lethargy that the animal showed for 48 h.
[6] Transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See package leaflet for respective contact details.

3.7. Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has been established in pregnant and lactating bitches.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8. Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by moxidectin.

3.9. Administration routes and dosage

Subcutaneous use.

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 veterinary medicinal 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 veterinary medicinal 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 an 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 veterinary 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.

3.10. Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration only by a veterinarian.

3.12. Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1. ATC vet code: QP54AB02

4.2. Pharmacodynamics

Moxidectin is a parasiticide active against a wide range of internal and external parasites and is a second-generation macrocyclic lacton of the milbemicins family.
Its main mode of action is to increase the permeability of the cell membrane to the chlorine ions in the postsynaptic junctions and induce an irreversible state of rest. This causes a flaccid paralysis and ultimately the death of the parasite exposed to the substance. There is no other evidence that moxidectin has other effects on any of the tissues or organs of the mammals. Moxidectin at the dose of 0.17 mg/kg b.w. is effective in preventing infections by migrating *D. immitis* larvae. No effect on adult parasitic forms are found at the recommended doses. Moxidectin is also active against some G.I. nematodes present in the dog.

4.3. Pharmacokinetics

Moxidectin is a highly lipophilic compound with residues predominantly found in fat compared to other tissues. Following the administration of the veterinary medicinal product, moxidectin is absorbed from the inoculum site and is subject to limited biotransformations by means of hydroxylation.
Hydroxylation is believed to occur in the liver. The only significant way to excretion is through the stools. The moxidectin blood concentration values were measured in the dog following treatment with the veterinary medicinal product. The serum levels of moxidectin are dose-dependent. The highest concentration was found 10 days after treatment. The blood peak of 4.13 ng/ml decreased continuously during the study (180 days). The last day with quantifiable concentrations was day 165.

Environmental properties

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

5. PHARMACEUTICAL PARTICULARS

5.1. Major incompatibilities

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

5.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 3 months.

5.3. Special precautions for storage

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).

5.4. Nature and composition of immediate packaging

Powder (microspheres) vial:
6 ml Type I brown glass vial containing 197.3 mg of microspheres, closed with a Type I chlorobutyl rubber stopper and a flip-off aluminium collar.

20 ml Type II brown glass vial containing 592 mg of microspheres, closed with a Type I chlorobutyl rubber stopper and a flip-off aluminium collar.

Solvent vial:
6 ml Type I colourless glass vial containing 5.67 ml, of solvent closed with a Type I chlorobutyl rubber stopper and a flip-off aluminium collar.

20 ml Type II colourless glass vial, containing 17 ml of solvent closed with a Type I chlorobutyl rubber stopper and a flip-off aluminium collar.

Package sizes:
Cardboard box with 1 powder vial of 197.3 mg, 1 solvent vial of 5.67 ml and 1 adapter.
Cardboard box with 1 powder vial of 197.3 mg, 1 solvent vial of 5.67 ml and 1 adapter, 1 syringe and 1 needle.
Cardboard box with 1 powder vial of 592 mg, 1 solvent vial of 17 ml and 1 adapter.
Cardboard box with 1 powder vial of 592 mg, 1 solvent vial of 17 ml and 1 adapter, 1 syringe and 1 needle.

Not all pack sizes may be marketed.

5.5. Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

The veterinary medicinal product should not enter water courses as moxidectin 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 applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

FATRO S.p.A.

7. MARKETING AUTHORISATION NUMBER (S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1 powder vial + 1 solvent vial + adapter

1 powder vial + 1 solvent vial + adapter + syringe + needle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Afilaria liberación prolongada 3.4 mg/ml powder and solvent for suspension for injection (ES).
Afilaria SR 3.4 mg/ml powder and solvent for suspension for injection (AT, BG, CZ, EL, FR, HR, HU, PT, RO, SI, SK).
Prevengo SR 3.4 mg/ml powder and solvent for suspension for injection (IT).

2. STATEMENT OF ACTIVE SUBSTANCES

Each vial of powder of 197.3 mg of microspheres contains:

Active substance:
Moxidectin 19.73 mg

Each vial of powder of 592 mg of microspheres contains:

Active substance:
Moxidectin 59.2 mg

Each ml of the reconstituted suspension contains:

Active substance:
Moxidectin 3.4 mg

3. PACKAGE SIZE

1 powder vial 197.3 mg + 1 solvent vial 5.67 ml + adapter
1 powder vial 197.3 mg + 1 solvent vial 5.67 ml + adapter + syringe + needle
1 powder vial 592 mg + 1 solvent vial 17 ml + adapter
1 powder vial 592 mg + 1 solvent vial 17 ml + adapter + syringe + needle

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTE OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within: 3 months.
Use by…

9. SPECIAL STORAGE PRECAUTIONS

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).

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

FATRO S.p.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label
Powder vial 197.3 mg
Powder vial 592 mg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Afilaria liberación prolongada (ES).
Afilaria SR (AT, BG, CZ, EL, FR, HR, HU, PT, RO, SI, SK).
Prevengo SR (IT).

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each vial of powder contains:
197.3 mg of microspheres equivalent to 19.73 mg of Moxidectin
592 mg of microspheres equivalent to 59.2 mg of Moxidectin

Each ml of the reconstituted suspension contains 3.4 mg of Moxidectin.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within: 3 months.
Use by…

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label
Solvent vial 5.67 ml
Solvent vial 17 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for
Afilaria liberación prolongada (ES).
Afilaria SR (AT, BG, CZ, EL, FR, HR, HU, PT, RO, SI, SK).
Prevengo SR (IT).

2. WEIGHT, VOLUME OR NUMBER OF DOSES

5.67 ml
17 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Afilaria liberación prolongada 3.4 mg/ml powder and solvent for suspension for injection for dogs (ES).
Afilaria SR 3.4 mg/ml powder and solvent for suspension for injection for dogs (AT, BG, CZ, EL, FR, HR, HU, PT, RO, SI, SK).
Prevengo SR 3.4 mg/ml powder and solvent for suspension for injection for dogs (IT).

2. Composition

Each vial of powder of 197.3 mg of microspheres contains:

Active substance:
Moxidectin 19.73 mg

Each vial of powder of 592 mg of microspheres contains:

Active substance:
Moxidectin 59.2 mg

Each vial of solvent (5.67 ml or 17 ml) contains:

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

Each ml of the reconstituted suspension contains:

Active substance:
Moxidectin 3.4 mg

Excipients:
Methyl parahydroxybenzoate (E218) 1.82 mg/ml
Propyl parahydroxybenzoate 0.21 mg/ml

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

3. Target species

Dogs.

4. Indications for use

For the prevention of heartworm disease (L3 and L4 larvae of *Dirofilaria immitis*).
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 veterinary medicinal product has demonstrated persistent efficacy for the whole duration of the risk of infection season for the heartworm disease caused by *D. immitis* 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. 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 body weight, 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. 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 safe use in target species:
The veterinary medicinal product must be used only in controlled dogs which were negative at the test for heartworm disease. Before starting the prophylactic treatment with the veterinary medicinal product, infected dogs must be treated to remove adult heartworms and microfilariae. These treatments must be performed under the Veterinary Surgeon's responsibility.

The veterinary medicinal product has demonstrated to be very safe even for species sensitive to ivermectins and animals resulted positive to test for heartworm disease.

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 veterinary medicinal 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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has been established in pregnant and lactating bitches.
Can be used during pregnancy and lactation.

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.

Special restriction for use and special conditions for use:
For administration only by a veterinarian.

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

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Injection site granuloma [1]. Injection site pain[2], Injection site swelling[2].
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reaction[3], Angioedema, Urticaria, Anaphylaxis[4]; Itching; Lethargy.Anorexia[5]
Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea, Vomiting; Ataxia[6], Tremor.

[1] Usually well-defined and of small dimension, the average severity of lesions was registered as "modest".
[2] Short-lived pain at the injection site or a slight moderate local reaction (swelling) for 2-3 weeks.
[3] Possible local reactions (i.e. face, mucosae, legs, testis, eyelids, lips).
[4] If such reaction occurs, appropriate treatment should be administered without delay.
[5] It is reasonable to assume that it was a consequence of the lethargy that the animal showed for 48 h.
[6] Transient.

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

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 veterinary medicinal 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 veterinary medicinal 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 veterinary 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 veterinary medicinal product must be used only in controlled dogs which were negative at the test for heartworm disease. Before starting the prophylactic treatment with the veterinary medicinal 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 periods

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.

12. Special precautions for disposal

Medicines should not be disposed via wastewater or household waste.
This veterinary medicinal product should not enter water courses as moxidectin 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 applicable 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 authorization numbers and pack sizes

MA number:

Package sizes:
Cardboard box with 1 powder vial of 197.3 mg, 1 solvent vial of 5.67 ml and 1 adapter.
Cardboard box with 1 powder vial of 197.3 mg, 1 solvent vial of 5.67 ml and 1 adapter, 1 syringe and 1 needle.
Cardboard box with 1 powder vial of 592 mg, 1 solvent vial of 17 ml and 1 adapter.
Cardboard box with 1 powder vial of 592 mg, 1 solvent vial of 17 ml and 1 adapter, 1 syringe and 1 needle.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last approved

{MM/YYYY}

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:
FATRO S.p.A.
Via Emilia, 285
40064 Ozzano dell'Emilia (Bologna), Italy.

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information

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

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 veterinary medicinal 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.