

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 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).

Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram of powder (microspheres) contains:

Active substance: moxidectin 100 mg

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

3. PHARMACEUTICAL FORM

Powder and solvent for suspension for injection

4. PACKAGE SIZE

1 powder vial 592 mg + 1 solvent vial 17 ml + adapter

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

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

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous use.

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Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING, IF NECESSARY

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

Read the package leaflet before use.

10. EXPIRY DATE

EXP. {month/year}

Shelf life after reconstitution according to directions: 3 months

Once reconstituted use by: _____

11. SPECIAL STORAGE CONDITIONS

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).

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste materials in accordance with local requirements.

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

To be supply only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBERS

17. MANUFACTURER'S BATCH NUMBER

LOT. {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label Powder vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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).
Moxidectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each gram of powder (microspheres) contains:
Active substance: moxidectin 100 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

592 mg (equivalent to 59.2 mg of moxidectin)

197.3 mg (equivalent to 19.73 mg of moxidectin)

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

LOT. {number}

7. EXPIRY DATE

EXP. {month/year}

Shelf life after reconstitution according to directions: 3 months

Once reconstituted use by: _____

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label Solvent vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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).

Moxidectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml of solvent contains:

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

17 ml

5.67 ml

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

LOT. {number}

7. EXPIRY DATE

EXP. {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.