AFILARIA SR 3.4 mg/ml powder and solvent for suspension for injection for dogs

Authorised

- Moxidectin

Product identification

Medicine name:
AFILARIA SR 3.4 mg/ml powder and solvent for suspension for injection for dogs

Active substance:
Moxidectin

Target species:
Dog

Route of administration:
Subcutaneous use

Product details

Active substance and strength:
Moxidectin
100.00 milligram(s)/gram / 1.00 gram(s)

Pharmaceutical form:

Powder and solvent for suspension for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP54AB02

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Romania

Available in:
Romania

Package description:
Cardboard box with 1 powder vial containing 197,3 mg, 1 solvent vial with 5,67 ml and 1 adapter for reconstitution and withdrawal, 1 syringe and 1 needle.
Cardboard box with 1 powder vial containing 197,3 mg, 1 solvent vial with 5,67 ml and 1 adapter for reconstitution and withdrawal.
Cardboard box with 1 powder vial containing 592 mg, 1 solvent vial with 17 ml and 1 adapter for reconstitution and withdrawal, 1 syringe and 1 needle.
Cardboard box with 1 powder vial containing 592 mg, 1 solvent vial with 17 ml and 1 adapter for reconstitution and withdrawal.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Fatro S.p.A.

Marketing authorisation date:

15/03/2022

Manufacturing sites for batch release:
Fatro S.p.A.

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
220058

Date of authorisation status change:
28/01/2026

Reference member state:
Spain

Procedure number:
ES/V/0315/001

Concerned member states:
Austria Bulgaria Croatia Czechia France Greece Hungary Italy Portugal Romania Slovakia Slovenia

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Package Leaflet

Labelling

Combined File of all Documents

English (PDF)
Published on: 3/12/2025
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