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

Authorised

- Moxidectin

Product identification

Medicine name:
GUARDIAN 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
10.00 gram(s) / 100.00 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:
Greece

Available in:
Greece

Package description:
Type I glass vial of 20 ml containing not less than 538 mg of moxidectin microsphere (equal to 59.2 mg of moxidectin) and type I glass vial of 28.5 ml containing not less than 17 ml of vehicle

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Elanco GmbH

Marketing authorisation date:
9/01/2011

Manufacturing sites for batch release:
Elanco France S.A.S.

Responsible authority:

National Organization For Medicines

Authorisation number:
1240/10-01-2011/K-0154005

Date of authorisation status change:
1/10/2023

Reference member state:
Italy

Procedure number:
IT/V/0111/001

Concerned member states:
France Greece Portugal Spain

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

Documents

Combined File of all Documents

Summary of Product Characteristics

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Package Leaflet

This document does not exist in this language (English). You can find it in another language below.