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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

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

Package Leaflet

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