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DALMARELIN 25 micrograms/ml solution for injection for cattle and rabbits

Authorised

- Lecirelin

Product identification

Medicine name:
DALMARELIN 25 micrograms/ml solution for injection for cattle and rabbits

Active substance:
Lecirelin

Target species:
Rabbit
Cattle

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Lecirelin
25.00 microgram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Rabbit**
  - Meat and offal. 0 day
- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QH01CA92

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

Authorisation status:
Valid

Authorised in:
Malta

Package description:
100 ml High Density Polyethylene (HDPE) collapsible container closed with a type I rubber stopper and an aluminium overseal, in a cardboar box.
20 ml type II neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboar box.
5 x 10 ml type I neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboar box.
10 ml type I neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboar box.
10 x 4 ml type I neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboar box.

4 ml type I neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboar box.
50 ml type II neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboar box.

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:
Fatro S.p.A.

Marketing authorisation date:
30/05/2022

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

Responsible authority:
Veterinary And Phytosanitary Regulation Department

Authorisation number:
VMA 134

Date of authorisation status change:
21/10/2024

Reference member state:
Italy

Procedure number:
IT/V/0112/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Finland France

Germany Hungary Iceland Ireland Luxembourg Malta Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden

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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