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:
Sweden

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:
15/08/2023

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

Responsible authority:
Swedish Medical Products Agency

Authorisation number:
62988

Date of authorisation status change:
15/08/2023

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

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.

Labelling

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

Combined File of all Documents