

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:**

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Rabbit

- Meat and offal. 0 day

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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 except for some pack sizes

Authorisation status:

Valid

Authorised in:

Norway

Package description:

100 ml High Density Polyethylene (HDPE) collapsible container closed with a type I rubber stopper and an aluminium overseal, in a cardboard box.

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

5 x 10 ml type I neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboard box.

10 ml type I neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboard box.

10 x 4 ml type I neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboard box.

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

50 ml type II neutral colourless glass vials, closed with a type I rubber stopper and an aluminium overseal, in a cardboard 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:

12/09/2023

Manufacturing sites for batch release:

Fatro S.p.A.

Responsible authority:

Norwegian Medical Products Agency

Authorisation number:

22-14581

Date of authorisation status change:

12/09/2023

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

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

Documents

Combined File of all Documents