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Dalmaprost 0.075 mg/ml solution for injection for cattle, pigs and horses

Authorised

- R-Cloprostenol sodium

Product identification

Medicine name:
Dalmaprost 0.075 mg/ml solution for injection for cattle, pigs and horses

Active substance:
R-Cloprostenol sodium

Target species:
Cattle (cow)
Pig (female)
Horse (mare)

Route of administration:
Intramuscular use

Product details

Active substance and strength:
R-Cloprostenol sodium
0.08 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle (cow)**
  - Meat and offal. no withdrawal period — withdrawal period is 0 days
  - Milk. no withdrawal period — withdrawal period is 0 hours
- **Pig (female)**
  - Meat and offal. 1 day
- **Horse (mare)**
  - Meat and offal. 2 day
  - Milk. no withdrawal period — withdrawal period is 0 hours

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Anatomical therapeutic chemical veterinary (ATCvet) codes:
QG02AD90

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

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Authorisation status:
Valid

Authorised in:
Malta

Package description:
box containing 15 vials of 2 ml
box containing 60 vials of 2 ml
box containing 1 vial of 10 ml
box containing 1 vial of 20 ml

box containing 1 HDPE container of 100 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Fatro S.p.A.

Marketing authorisation date:
13/05/2020

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

Responsible authority:
Veterinary And Phytosanitary Regulation Department

Authorisation number:
VMA71

Date of authorisation status change:
13/05/2020

Reference member state:
Spain

Procedure number:
ES/V/0305/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Malta Netherlands Norway Poland Portugal Romania Slovakia Slovenia Sweden United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

Package Leaflet

Labelling

Combined File of all Documents

eu-PUAR-dalmaprost-0.075-mg-ml-solution-for-injection-for-cattle--pigs-and-horses-en.pdf