

# 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

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**Active substance:**

R-Cloprostenol sodium

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**Target species:**

Cattle (cow)

Pig (female)

Horse (mare)

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**Route of administration:**

Intramuscular use

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## Product details

**Active substance and strength:**

R-Cloprostenol sodium

0.08 milligram(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Solution for injection

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**Withdrawal period by route of administration:****Intramuscular use:**

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**Cattle (cow)**

- Meat and offal. no withdrawal period withdrawal period is 0 days

- Milk. no withdrawal period withdrawal period is 0 hours

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**Pig (female)**

- Meat and offal. 1 day

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**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

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Ireland

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**Available in:**

Ireland

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**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

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Fatro S.p.A.

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**Marketing authorisation date:**

13/09/2019

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**Manufacturing sites for batch release:**

Fatro S.p.A.

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**Responsible authority:**

Health Products Regulatory Authority

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**Authorisation number:**

VPA10836/009/001

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**Date of authorisation status change:**

13/09/2019

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**Reference member state:**

Spain

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**Procedure number:**

ES/V/0305/001

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**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)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://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