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

Authorised

D-CLOPROSTENOL SODIUM SALT

#### Product identification

#### **Medicine name:**

Dalmaprost 0.075 mg/ml solution for injection for cattle, pigs and horses Dalmazin SYNCH, 0,075 mg/mL, otopina za injekciju, za goveda, svinje i konje

#### **Active substance:**

**D-CLOPROSTENOL SODIUM SALT** 

#### **Target species:**

Cattle (cow)

Pig (female)

Horse (mare)

#### Route of administration:

Intramuscular use

#### **Product details**

#### **Active substance and strength:**

D-CLOPROSTENOL SODIUM SALT 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  $% \left( 1\right) =\left( 1\right) \left( 1\right) +\left( 1\right) \left( 1\right) \left( 1\right) +\left( 1\right) \left( 1\right) \left$

#### Anatomical therapeutic chemical veterinary (ATCvet) codes:

**QG02AD90** 

#### Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

#### **Authorisation status:**

Valid

#### Authorised in:

Croatia

#### **Available in:**

Croatia

#### Package description:

box containing 1 HDPE container of 100 ml

box containing 1 vial of 20 ml

box containing 1 vial of 10 ml

box containing 60 vials of 2 ml

box containing 15 vials of 2 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:

24/09/2019

#### Manufacturing sites for batch release:

Fatro S.p.A.

#### **Responsible authority:**

Ministry Of Agriculture Veterinary And Food Safety Directorate

#### **Authorisation number:**

UP/I-322-05/19-01/590

#### Date of authorisation status change:

29/07/2021

#### 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 English (PDF) Published on: 12/04/2023 Download Package Leaflet Labelling eu-PUAR-dalmaprost-0.075-mg-ml-solution-for-injection-for-cattle--pigs-and-horsesen.pdf

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