Galapan 75 micrograms/ml solution for injection for cattle, horses and pigs

Authorised

- R-Cloprostenol sodium

Product identification

Medicine name:
Galapan 75 micrograms/ml solution for injection for cattle, horses and pigs
Galapan 75 micrograms/ml solution for injection for cattle, horses and pigs

Active substance:
R-Cloprostenol sodium

Target species:
Cattle
Horse
Pig

Route of administration:
Intramuscular use

Product details

Active substance and strength:
R-Cloprostenol sodium

78.88 microgram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 1 day (Meat and offal)
  - Milk. 0 hour
- **Horse**
  - Meat and offal. 1 day
  - Milk. 0 hour
- **Pig**
  - Meat and offal. 1 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QG02AD90

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

Authorisation status:
Valid

Authorised in:
Ireland

Package description:
Colourless vials of type I glass containing 20 ml of solution for injection, with chlorobutyl rubber stoppers and aluminium caps. Presentation: Cardboard box of 1 vial of 20 ml

Colourless vials of type I glass containing 50 ml of solution for injection, with chlorobutyl rubber stoppers and aluminium caps. Presentation: Cardboard box of 1 vial of 50 ml
Colourless vials of type I glass containing 20 ml of solution for injection, with chlorobutyl rubber stoppers and aluminium caps. Presentation: Cardboard box of 5 vials of 20 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Informed Consent application (Article 21 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Industrial Veterinaria S.A.

Marketing authorisation date:
1/08/2025

Manufacturing sites for batch release:
Industrial Veterinaria S.A.
Industrial Veterinaria S.A.
aniMedica GmbH

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10509/010/001

Date of authorisation status change:
1/08/2025

Reference member state:
Ireland

Procedure number:

IE/V/0630/001

Concerned member states:
Spain

Informed consent reference:
600000050164
600000050164

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

Documents

Summary of Product Characteristics

Combined File of all Documents

ie-puar-mr-iev0630001-galapan-75-microgramsml-solution-for-injection-for-en.pdf