PRONESTESIC 40 mg/ml + 0.036 mg/ml solution for injection for horses, cattle, swine and sheep

Authorised

- Procaine hydrochloride
- ADRENALINE TARTRATE PH. EUR.

Product identification

Medicine name:
PRONESTESIC 40 mg/ml + 0.036 mg/ml solution for injection for horses, cattle, swine and sheep

Active substance:
Procaine hydrochloride
ADRENALINE TARTRATE PH. EUR.

Target species:
Cattle
Sheep
Pig
Horse

Route of administration:
Perineural use
Subcutaneous use

Product details

Active substance and strength:
Procaine hydrochloride
40.00 milligram(s) / 1.00 millilitre(s)

ADRENALINE TARTRATE PH. EUR.
0.04 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Perineural use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 day
- **Sheep**
  - Meat and offal. 0 day
  - Milk. 0 day
- **Pig**
  - Meat and offal. 0 day
- **Horse**
  - Meat and offal. 0 day
  - Milk. 0 day

Subcutaneous use:

- **Cattle**

- Meat and offal. 0 day
- Milk. 0 day

- **Sheep**
  - Meat and offal. 0 day
  - Milk. 0 day

- **Pig**
  - Meat and offal. 0 day

- **Horse**
  - Meat and offal. 0 day
  - Milk. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN01BA52

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

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Authorisation status:
Valid

Authorised in:
Norway

Available in:
Norway

Package description:
box containing 10 vials of 100 ml
box containing 1 vial of 250 ml
box containing 1 vial of 100 ml
box containing 1 vial of 50 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:
14/03/2016

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

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
15-10642

Date of authorisation status change:
24/02/2021

Reference member state:
Spain

Procedure number:
ES/V/0238/001

Concerned member states:
Austria Belgium Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Iceland Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal 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: 22/12/2023
Download

Package Leaflet

English (PDF)
Published on: 25/12/2023
Download

Labelling

Combined File of all Documents

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