Pronestesic 40 mg/ml / 0.036 mg/ml Solution for Injection for Horses, Cattle, Pigs 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, Pigs 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

---

Authorisation status:
Valid

Authorised in:
United Kingdom (Northern Ireland)

Available in:
United Kingdom (Northern Ireland)

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:
20/04/2016

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

Responsible authority:
The Veterinary Medicines Directorate

Authorisation number:
Vm 11557/4002

Date of authorisation status change:
10/11/2023

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

Package Leaflet

Labelling

Combined File of all Documents

eu-PUAR-esv0238001-dcp-pronestesic-40-mg-ml-+-0.036-mg-ml-solution-for-injection-for-horses--cattle--swine-and-sheep-en.pdf