

# 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

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### Active substance:

Procaine hydrochloride  
ADRENALINE TARTRATE PH. EUR.

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### Target species:

Cattle  
Sheep  
Pig  
Horse

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### Route of administration:

Perineural use  
Subcutaneous use

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## 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)

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### **Pharmaceutical form:**

Solution for injection

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### **Withdrawal period by route of administration:**

#### **Perineural use:**

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#### **Cattle**

- Meat and offal. 0 day

- Milk. 0 day

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#### **Sheep**

- Meat and offal. 0 day

- Milk. 0 day

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#### **Pig**

- Meat and offal. 0 day

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#### **Horse**

- Meat and offal. 0 day

- Milk. 0 day

#### **Subcutaneous use:**

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#### **Cattle**

- Meat and offal. 0 day

- Milk. 0 day

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**Sheep**

- Meat and offal. 0 day

- Milk. 0 day

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**Pig**

- Meat and offal. 0 day

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**Horse**

- Meat and offal. 0 day

- Milk. 0 day

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

QN01BA52

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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:**

Iceland

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**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

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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:**

4/04/2016

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**Manufacturing sites for batch release:**

Fatro S.p.A.

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**Responsible authority:**

Icelandic Medicines Agency

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**Authorisation number:**

IS/2/16/001/01

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**Date of authorisation status change:**

4/04/2016

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**Reference member state:**

Spain

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**Procedure number:**

ES/V/0238/001

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**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)

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