

# PRIMOPEN 300 mg/ml suspension for injection for cattle, pigs and horses

Authorised

- Benzylpenicillin procaine monohydrate

## Product identification

**Medicine name:**

PRIMOPEN 300 mg/ml suspension for injection for cattle, pigs and horses

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**Active substance:**

Benzylpenicillin procaine monohydrate

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**Target species:**

Cattle

Horse

Pig

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**Route of administration:**

Intramuscular use

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## Product details

**Active substance and strength:**

Benzylpenicillin procaine monohydrate

300.00 milligram(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Suspension for injection

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**Withdrawal period by route of administration:****Intramuscular use:**

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**Cattle**

- Meat and offal. 6 day 6 days for treatment duration 3-5 days.
- Meat and offal. 8 day 8 days for treatment duration 6-7 days.
- Milk. 4 day

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**Horse**

- Meat and offal. 180 day 180 days for treatment duration 3-5 days.
- Meat and offal. 182 day 182 days for treatment duration 6-7 days.

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**Pig**

- Meat and offal. 4 day 4 days for treatment duration 3-5 days.
- Meat and offal. 6 day 6 days for treatment duration 6-7 days.

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

QJ01CE09

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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:**

Poland

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**Package description:**

Available only in Polish

Available only in Polish

Available only in Polish

Available only in Polish

Available only in Polish

Colourless polyethylene terephthalate (PET) bottle, closed with chlorobutyl rubber stopper (Type I) and flip-off aluminium collar with tamper-evident polypropylene seal, in a cardboard box.Pack-size:1 x 100 ml PET bottle

Colourless polyethylene terephthalate (PET) bottle, closed with chlorobutyl rubber stopper (Type I) and flip-off aluminium collar with tamper-evident polypropylene seal, in a cardboard box.Pack-size:1 x 250 ml PET bottle

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## Additional information

### **Entitlement type:**

Marketing Authorisation

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### **Legal basis of product authorisation:**

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

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### **Marketing authorisation holder:**

Fatro S.p.A.

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### **Marketing authorisation date:**

15/12/2020

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### **Manufacturing sites for batch release:**

Fatro S.p.A.

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### **Responsible authority:**

Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

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### **Authorisation number:**

3061

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### **Date of authorisation status change:**

15/12/2020

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### **Reference member state:**

Ireland

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**Procedure number:**

IE/V/0640/001

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**Concerned member states:**

Denmark Greece Italy Norway Poland Spain

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

English (PDF)

Published on: 25/09/2024

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Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Labelling

This document does not exist in this language (English). You can find it in another language below.

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