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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

Active substance:
Benzylpenicillin (procaine) monohydrate

Target species:
Cattle
Horse
Pig

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Benzylpenicillin (procaine) monohydrate
300.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Suspension for injection

Withdrawal period by route of administration:

Intramuscular use:

- **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
- **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.
- **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.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01CE09

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

Authorisation status:
Valid

Authorised in:
Denmark

Available in:

Denmark

Package description:
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
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) bottles, closed with chlorobutyl rubber stopper (Type I) and flip-off aluminium collar with tamper-evident polypropylene seal, in a cardboard boxes.Pack-size:6 x 250 ml PET bottle
Colourless polyethylene terephthalate (PET) bottles, closed with chlorobutyl rubber stopper (Type I) and flip-off aluminium collar with tamper-evident polypropylene seal, in a cardboard boxes.Pack-size:30 x 100 ml PET bottle
Colourless polyethylene terephthalate (PET) bottles, closed with chlorobutyl rubber stopper (Type I) and flip-off aluminium collar with tamper-evident polypropylene seal, in a cardboard boxes.Pack-size:10 x 100 ml PET bottle
Type II colourless glass 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 glass bottle
Type II colourless glass 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 glass bottle

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Fatro S.p.A.

Marketing authorisation date:
30/09/2020

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

Responsible authority:
Danish Medicines Agency

Authorisation number:
63269

Date of authorisation status change:
30/09/2020

Reference member state:
Ireland

Procedure number:
IE/V/0640/001

Concerned member states:
Denmark Greece Italy Norway Poland Spain
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)
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Updated on: 14/03/2026
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