

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:**

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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.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01CE09

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Norway

Available in:

Norway

Package description:

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

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

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

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:6 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) 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

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:

23/09/2020

Manufacturing sites for batch release:

Fatro S.p.A.

Responsible authority:

Norwegian Medical Products Agency

Authorisation number:

19-13024

Date of authorisation status change:

23/09/2020

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)

Published on: 25/09/2024

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Package Leaflet

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