

Procapen, 300 mg/ml, Suspension for injection for cattle, pigs and horses

Authorised

- Benzylpenicillin procaine monohydrate

Product identification

Medicine name:

Procapen, 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

- Milk. 6 day
- Meat and offal. 14 day
- Meat and offal. 16 day

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Horse

- Milk. no withdrawal period

Not authorised for use in mares producing milk for human consumption.

- Meat and offal. 14 day
- Meat and offal. 16 day

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Pig

- Meat and offal. 15 day
- Meat and offal. 17 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01CE09

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Malta

Package description:

(ID8) 3000 millilitre(s): Box (Cardboard) with 12 Vial (Polypropylen) each with 250 millilitre(s), closed with Stopfen (bromobutyl rubber`)

(ID7) 3000 millilitre(s): Box (Cardboard) with 12 Vial (Glass) each with 250 millilitre(s), closed with Stopfen (bromobutyl rubber`)

(ID6) 250 millilitre(s): Box (Cardboard) with 1 Vial (Polypropylen) with 250 millilitre(s), closed with Stopfen (bromobutyl rubber`)

(ID5) 250 millilitre(s): Box (Cardboard) with 1 Vial (Glass) with 250 millilitre(s), closed with Stopfen (bromobutyl rubber`)

(ID4) 1200 millilitre(s): Box (Cardboard) with 12 Vial (Polypropylen) each with 100 millilitre(s), closed with Stopfen (bromobutyl rubber`)

(ID3) 100 millilitre(s): Box (Cardboard) with 1 Vial (Polypropylen) with 100 millilitre(s), closed with Stopfen (bromobutyl rubber`)

(ID2) 1200 millilitre(s): Box (Cardboard) with 12 Vial (Glass) each with 100 millilitre(s), closed with Stopfen (bromobutyl rubber`)

(ID1) 100 millilitre(s): Box (Cardboard) with 1 Vial (Glass) with 100 millilitre(s), closed with Stopfen (bromobutyl rubber`)

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:

aniMedica GmbH

Marketing authorisation date:

4/07/2019

Manufacturing sites for batch release:

aniMedica GmbH

Industrial Veterinaria S.A.

aniMedica Herstellungs GmbH

Responsible authority:

Veterinary And Phytosanitary Regulation Department

Authorisation number:

VMA78

Date of authorisation status change:

4/07/2019

Reference member state:

Germany

Procedure number:

DE/V/0126/001

Concerned member states:

Austria Bulgaria Cyprus Czechia Denmark Estonia Finland Greece Hungary
Italy Latvia Lithuania Malta Netherlands Poland Portugal Romania Slovakia
Slovenia Spain

To consult adverse reactions on veterinary medicinal products please go to
www.adrreports.eu/vet

Documents

Combined File of all Documents