

Orbenin LA 200 mg intramammary suspension for lactating cattle and sheep

Authorised

- Cloxacillin sodium monohydrate

Product identification

Medicine name:

Orbenin LA 200 mg intramammary suspension for lactating cattle and sheep

Active substance:

Cloxacillin sodium monohydrate

Target species:

Cattle (dairy cow)

Sheep

Route of administration:

Intramammary use

Product details

Active substance and strength:

Cloxacillin sodium monohydrate

210.08 milligram(s) / 1.00 Applicator

Pharmaceutical form:

Intramammary suspension

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

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Cattle (dairy cow)

- Milk. 96 hour
- Meat and offal. 7 day

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Sheep

- Meat and offal. 7 day
- Milk. no withdrawal period

Not authorised for use in sheep producing milk for human consumption

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ51CF02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Portugal

Package description:

(ID1) 36 gram(s): unspecified outer container with 12 Applicator (Low Density PolyEthylene) each with 3 gram(s)

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:

Zoetis Portugal Lda.

Marketing authorisation date:

8/11/2019

Manufacturing sites for batch release:

Haupt Pharma Latina S.r.l.

Responsible authority:

Directorate General For Food And Veterinary

Authorisation number:

1312/01/19RFVPT

Date of authorisation status change:

17/10/2022

Reference member state:

Germany

Procedure number:

DE/V/0319/001

Concerned member states:

Italy Netherlands Poland Portugal Spain

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

Documents

Combined File of all Documents

2402185-paren-20181101.rtf