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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:

- **Cattle (dairy cow)**
  - Milk. 96 hour
  - Meat and offal. 7 day
- **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