Cryptisel 0.5 mg/ml oral solution for calves

Authorised

- Halofuginone lactate

Product identification

Medicine name:
Cryptisel 0.5 mg/ml oral solution for calves
Cryptisel vet 0,5 mg/ml mikstur, oppløsning til kalv

Active substance:
Halofuginone lactate

Target species:
Cattle (newborn calf)

Route of administration:
Oral use

Product details

Active substance and strength:
Halofuginone lactate
0.61 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oral solution

Withdrawal period by route of administration:

Oral use:

- **Cattle (newborn calf)**
  - Meat and offal. 13 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP51BX01

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

Authorisation status:
Valid

Authorised in:
Norway

Package description:
box containing 1 bottle of 1000 ml (containing 980 ml of soluci?n)
box containing 1 bottle of 500 ml (containing 490 ml of soluci?n)
box containing 1 bottle of 300 ml (containing 290 ml of soluci?n)
box containing 1 bottle of 1000 ml (containing 980 ml of soluci?n) with a 4 ml metering pump
box containing 1 bottle of 500 ml (containing 490 ml of soluci?n) with a 4 ml metering pump
box containing 1 bottle of 300 ml (containing 290 ml of soluci?n) with a 4 ml metering pump

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:

Industrial Veterinaria S.A.

Marketing authorisation date:
27/05/2021

Manufacturing sites for batch release:
Industrial Veterinaria S.A.
aniMedica GmbH
aniMedica Herstellungs GmbH

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
19-13131

Date of authorisation status change:
27/05/2021

Reference member state:
Spain

Procedure number:
ES/V/0374/001

Concerned member states:
Austria Cyprus Czechia Denmark Estonia Germany Greece Hungary Ireland Italy Latvia Lithuania Netherlands Norway Poland Portugal Romania Slovakia Sweden 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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