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Halofusol 0.5 mg/ml oral solution for calves

Authorised

- Halofuginone lactate

Product identification

Medicine name:
Halofusol 0.5 mg/ml oral solution for calves

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:
Poland

Package description:
box containing 1 bottle of 250 ml
box containing 1 bottle of 250 ml with a 4 ml metering pump
box containing 1 bottle of 500 ml
box containing 1 bottle of 500 ml with a 4 ml metering pump
box containing 1 bottle of 1000 ml
box containing 1 bottle of 1000 ml with a 4 ml metering pump
bottle of 250 ml
bottle of 500 ml
bottle of 1000 ml

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:
Laboratorios Karizoo S.A.

Marketing authorisation date:
23/10/2020

Manufacturing sites for batch release:
Laboratorios Karizoo S.A.

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
3036

Date of authorisation status change:
23/10/2020

Reference member state:
Spain

Procedure number:
ES/V/0351/001

Concerned member states:
Belgium Cyprus Denmark Estonia France Germany Greece Hungary Ireland Italy Latvia Lithuania Netherlands Poland Portugal Romania

United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

Package Leaflet