# Halofusol 0.5 mg/ml oral solution for calves

• Halofuginone lactate

## **Product identification**

#### Medicine name:

Halofusol 0.5 mg/ml oral solution for calves Halofusol, 0,5 mg/ml suukaudne lahus vasikatele

### 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:

Estonia

#### Package description:

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

4/05/2020

#### Manufacturing sites for batch release:

Laboratorios Karizoo S.A.

#### **Responsible authority:**

State Agency Of Medicines

#### **Authorisation number:**

2234

#### Date of authorisation status change:

4/05/2020

#### **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 <u>www.adrreports.eu/vet</u>

## Documents

Summary of Product Characteristics

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