# Oxyfluke 34 mg/ml Oral Suspension for Cattle and Sheep

Authorised

- Oxyclozanide

## Product identification

**Medicine name:**
Oxyfluke 34 mg/ml Oral Suspension for Cattle and Sheep
Oxyfluke, 34 mg/mL, oralna suspenzija, za goveda i ovce

**Active substance:**
Oxyclozanide

**Target species:**
Cattle
Sheep

**Route of administration:**
Oral use

## Product details

**Active substance and strength:**
Oxyclozanide
34.00 milligram(s) / 1.00 millilitre(s)

**Pharmaceutical form:**

Oral suspension

**Withdrawal period by route of administration:**

**Oral use:**

- **Cattle**
  - Meat and offal. 13 day
  - Milk. 108 hour
- **Sheep**
  - Meat and offal. 14 day
  - Milk. 7 day

**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QP52AG06

**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

**Authorisation status:**

Valid

**Authorised in:**

Croatia

**Package description:**

White high density polyethylene backpacks (1 L) closed with white polypropylene screw caps. 1 x 1 L in a cardboard box

White high density polyethylene backpacks (2.5 L) closed with white polypropylene screw caps. 1 x 2.5 L in a cardboard box

White high density polyethylene backpacks (5 L) closed with white polypropylene screw caps. 1 x 5 L in a cardboard box

White high density polyethylene backpacks (5 L) closed with white polypropylene screw caps. 2 x 5 L in a cardboard box

## 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:**
Norbrook Laboratories (Ireland) Limited

**Marketing authorisation date:**
19/03/2018

**Manufacturing sites for batch release:**
Norbrook Laboratories Limited
Norbrook Manufacturing Limited

**Responsible authority:**
Ministry Of Agriculture Veterinary And Food Safety Directorate

**Authorisation number:**
UP/I-322-05/18-01/103

**Date of authorisation status change:**
9/09/2019

**Reference member state:**
Ireland

**Procedure number:**
IE/V/0601/001

**Concerned member states:**
Belgium Bulgaria Croatia Hungary Luxembourg Netherlands Portugal Slovenia Spain 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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