# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxyfluke 34 mg/ml Oral Suspension for Cattle and Sheep

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of product contains:

**Active substance:**

| | |
|---|---|
| Oxyclozanide | 34.0 mg |

**Excipients**:

| | |
|---|---|
| Methyl Parahydroxybenzoate | 1.5 mg |
| Propyl Parahydroxybenzoate | 0.15 mg |
| Sodium Metabisulphite | 1.0 mg |

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Oral suspension.
An off white to beige suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Target Species

Cattle and Sheep

### 4.2 Indications for use, specifying the target species

For the treatment of chronic fascioliasis caused by the adult stage of *Fasciola hepatica* susceptible to Oxyclozanide.

### 4.3 Contraindications

Do not use in known cases of hypersensitivity to oxyclozanide or to any of the excipients.

### 4.4 Special warnings for each target species

At normal dose levels, oxyclozanide is not active against immature flukes present in liver tissue.
Milking cattle, particularly high yielders, may occasionally show a reduction in yield of 5% or more for about 48 hours after handling. The effect of this small

loss may be minimised by spreading herd dosing over a period of about a week.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
Underdosing, which may be due to underestimation of body weight, misadministration of the product or lack of calibration of the dosing device (if any).
Suspected clinical cases of resistance to anthelmintics should be further investigates using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmaceutical class and having a different mode of action should be used.

To date no resistance to oxyclozanide has been reported. Use of the product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

## 4.5 Special precautions for use

Special precautions for use in animals

Care should be taken when administering by dosing gun to avoid damage to the pharyngeal region.

Due regard must be given to the physical condition of the animals undergoing treatment, particularly those in advanced pregnancy and / or under stress from adverse weather conditions, poor nutrition, penning, handling etc.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product can cause irritation to skin, eyes and mucous membranes. In case of contact, rinse the affected area immediately with plenty of water.
Contaminated clothing should be removed immediately.
Wash hands after use.
Wear impermeable gloves during use.
Do not eat, drink or smoke where handling the product.
People with known hypersensitivity to oxyclozanide or any of the excipients should avoid contact with the product.

Other precautions
Oxyclozanide may be toxic to dung fauna at high concentrations anticipated in dung. The possible risk to dung fauna can be reduced by avoiding too frequent and repeated use of Oxyclozanide in cattle.

## 4.6 Adverse reactions (frequency and seriousness)

At normal oxyclozanide dose levels, cattle may show slight softening of the faeces with the occasional animal showing increased frequency of defecation and transient inappetence.

## 4.7 Use during pregnancy, lactation or lay

Can be used in pregnancy or lactation. See section 4.5

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

Give as an oral drench. Shake the product well before use.

The body weight of animals should be assessed as accurately as possible before calculating the dosage. The accuracy of the dosing device should be checked.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Dose according to body weight at the rate of 10 mg oxyclozanide per kg body weight for cattle and 15 mg oxyclozanide per kg body weight for sheep as follows:-

Cattle : 3 ml per 10 kg body weight

For example:-

| **Body weight** | **Dose** |
|---|---|
| 50 kg | 15 ml |
| 100 kg | 30 ml |
| 150 kg | 45 ml |
| 200 kg | 60 ml |
| 250 kg | 75 ml |
| 300 kg | 90 ml |
| 350 kg and over | 105 ml |

Drench can be given in the feed to cattle which are fed individually. Pour the recommended dose onto their concentrate ration. Molasses or salt may be added for shy feeders.

Sheep: 4.5 ml per 10 kg body weight

For example:-

| Body weight | Dose |
|---|---|
| 10 kg | 4.5 ml |
| 20 kg) | 9.0 ml |
| 30 kg | 13.5 ml |
| 40 kg | 18.0 ml |
| 45 kg and over | 20.0 ml |

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The effects of oxyclozanide over-dosage are dullness and some loosening of faeces in sheep and possible diarrhoea, inappetance and loss of weight in cattle. These effects are occasionally enhanced in animals with severe liver damage and/or dehydration at the time of dosing. At higher doses the severity of signs of toxicity increased and mortality occurred at 50 mg/kg bw and higher.

## 4.11 Withdrawal period(s)

Cattle
Meat and offal: 13 days
Milk: 108 hours (4.5 days)

Sheep
Meat and offal: 14 days
Milk: 7 days

# 5. PHARMACOLOGICAL PROPERTIES

**Pharmacotherapeutic group:** Anthelmintics, Oxyclozanide

**ATCvet code:** QP52AG06

## 5.1 Pharmacodynamic properties

Oxyclozanide is an anthelmintic of the salicylanilide group. The chemical structure of salicylanilides is characterised by unstable proton. They are lipophilic molecules which allow the passage of protons across membranes, especially the inner mitochondrial membrane. The salicylanilides are proton ionophores, which act as uncouplers of mitochondrial oxidative phosphorylation, disrupting metabolism of the parasite.

Oxyclozanide has flukicidal activity against the adult stage of *Fasciola hepatica*.

## 5.2 Pharmacokinetic particulars

Oxyclozanide is slowly absorbed after oral administration with peak plasma levels 24 hours after dosing. Excretion is predominantly faecal, biliary excretion being the most important route of elimination (cattle studies only).

## 5.3 Environmental properties

Faeces containing oxyclozanide excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on dung degradation. Animals may be excreting oxyclozanide in dung, at levels that are potentially toxic to dung fauna, for up to 8 days post treatment.

Oxyclozanide is toxic to dung fauna and aquatic organisms. The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of oxyclozanide in cattle. The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for 5 days after treatment.

Oxyclozanide dissociates depending on pH. It may bioaccumulate in fish in acidic conditions.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Sodium metabisulphite
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Sodium laurilsulphate
Aluminium magnesium silicate
Carmellose sodium
Sodium citrate
Purified water

## 6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after first opening the container: 6 months

## 6.4 Special precautions for storage

Protect from light.

## 6.5 Nature and composition of immediate packaging

White high density polyethylene backpacks (1 L, 2,5 L and 5 L) closed with white polypropylene screw caps.

1 x 1 L in a cardboard box
1 x 2.5 L in a cardboard box
1 x 5 L in a cardboard box
2 x 5 L in a cardboard box

Not all pack sizes may be marketed.

## 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

## 8. MARKETING AUTHORISATION NUMBER

Vm 02000/4422

## 9. DATE OF FIRST AUTHORISATION

21 August 2017

## 10. DATE OF REVISION OF THE TEXT

March 2022

Approved 16 March 2022