# A. LABELLING

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**{Carton and/or Label for 1L, 2.5L, 5 L and 10L}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Niltrem 34 mg/ml oral suspension for cattle (UK)

Rumenil 34 mg/ml oral suspension for cattle (AT, BE, DE, FR, NL & RO)

Chanil 34 mg/ml oral suspension for cattle (BG & IE).

Oxyclozanide

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

**Active substance:**

| | |
|---|---|
| Oxyclozanide | 34.0 mg/ml |

**Excipients:**

| | |
|---|---|
| Methyl Parahydroxybenzoate (E218) | 2.0 mg/ml |
| Propyl Parahydroxybenzoate | 0.2 mg/ml |

## 3. PHARMACEUTICAL FORM

Oral suspension

A smooth uniform off-white to yellow suspension

## 4. PACKAGE SIZE

1L

2.5L

5 L

10 L

## 5. TARGET SPECIES

Cattle

## 6. INDICATIONS

Treatment of chronic fascioliasis caused by the adult stage of *Fasciola hepatica*, sensitive to oxyclozanide.
Elimination of gravid tapeworm segments (*Moniezia* spp).
Approved for use in dairy cattle
Treats adult liver fluke tapeworm.

## 7. METHOD AND ROUTES OF ADMINISTRATION

Oral Use. Shake the product well before use. To ensure administration of a correct dose, body weight should be determined as accurately as possible; 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 bodyweight at the rate of 10 mg oxyclozanide per kg bodyweight (cattle)

Cattle : 3 ml per 10 kg bodyweight;
For example:-
Bodyweight 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

## 8. WITHDRAWAL PERIODS

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

## 9. SPECIAL WARNING(S), IF NECESSARY

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 investigated 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 pharmacological class and having a different mode of action should be used.

At normal dose levels, oxyclozanide is not active against immature flukes present in liver tissue.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
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 *Fasciola* spp and recommendations on how to limit further selection for resistance to anthelmintics.

**Special precautions for use in animals**
Care should be taken when administering by dosing gun.
Due regard must always be given to the physical condition of animals undergoing treatment, particularly those in advanced pregnancy and/or under stress from adverse weather conditions, poor nutrition, penning, handling etc.
These effects are occasionally enhanced in animals suffering from severe liver damage and/or dehydration at the time of dosing.

**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 defaecation and transient inappetence.

Milking cattle, particularly high yielders, may show a reduction in yield, occasionally 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 one week.

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

Do not eat, drink or smoke where handling the product.

This veterinary medicinal product can cause irritation to skin, eyes and mucous membranes. In case of contact with the product, rinse the affected area immediately with plenty of water.

Contaminated clothing should be removed immediately.

Wash hands after use.

Wear impermeable gloves during use.

People with known hypersensitivity to oxyclozanide or any of the excipients should avoid contact with the veterinary medicinal product.

**Other precautions**

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.

**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.

Oxyclozanide is toxic to aquatic organisms. Oxyclozanide is persistent in soils.

**Use during pregnancy, lactation or lay**

Can be used during pregnancy or lactation. See special precautions for use in animals.

**Overdose (symptoms, emergency procedures, antidotes), if necessary**

The effects of oxyclozanide overdosage are possible diarrhoea, inappetence 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.

**Incompatibilities**

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

If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

## 10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 12 months.
Once opened, use by ____

## 11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Do not contaminate ponds, waterways or ditches.
Treated animals (cattle) should not have access to surface water for 5 days after treatment to avoid adverse effects on aquatic organisms.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

## 16. MARKETING AUTHORISATION NUMBER

Vm 08749/4076

## 17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Approved: 23 November 2017