A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND
PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR THE BATCH RELEASE, if different

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rumenil 34 mg/ml oral suspension for cattle.
Oxyclozanide

3. 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

4. PHARMACEUTICAL FORM

Oral suspension
A smooth uniform off-white to yellow suspension

5. PACKAGE SIZE

1L
2.5L
5 L
10 L

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. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients

8. ADVERSE REACTIONS

Adverse reactions (frequency and seriousness)
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.

If you notice any side effects, even those not already listed on this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. TARGET SPECIES

Cattle

10. DOSAGE FOR EACH SPECIES, ROUT(S) AND METHOD OF ADMINISTRATION

Oral 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

11. ADVICE ON CORRECT ADMINISTRATION

Shake the product well before use.

12. WITHDRAWAL PERIODS

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

13. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions
Do not use this veterinary medicinal product after the expiry date which is stated on the Label.
The expiry date refers to the last day of that month.

14. SPECIAL WARNING(S)

Special warnings for each target species
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.

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.

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

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

This veterinary medicinal product can cause irritation to skin, eyes and mucous membranes. Wear impermeable gloves during use.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.

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

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.

Target animals treated with oxyclozanide at the recommended therapeutic doses in several phases of reproduction showed no evidence of foetotoxicity, teratogenicity or effects on fertility

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.

Major incompatibilities

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

15. 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.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

February 2021

17. OTHER INFORMATION

1L, 2.5L & 5L: White High Density Polyethylene HDPE flexi containers with Polypropylene cap
and a PVDC seal
10 L: High Density Polyethylene (HDPE) container with a HDPE cap and an aluminium foil seal.
The product can be marketed with or without an outer carton.
Not all pack sizes may be marketed

The other ingredients (excipients) are: Sodium laurilsulfate, Propylene Glycol, Sodium Citrate, Disodium Edetate, Carmellose Sodium, Aluminium Magnesium Silicate, Simeticone and Purified Water

18. THE WORD "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

19. THE WORD "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

20. EXPIRY DATE

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

21. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4077

22. MANUFACTURER'S BATCH NUMBER

Lot {number}

Approved: 06/05/21