SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rumenil 34 mg/ml oral suspension for cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Oxyclozanide	34.0 mg

Excipient:

Methyl Parahydroxybenzoate (E218)	2.0 mg
Propyl Parahydroxybenzoate	0.2 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension

A smooth uniform off-white to yellow suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

Indications:

Treatment of chronic fascioliasis caused by the adult stage of *Fasciola hepatica*, sensitive to oxyclozanide.

Elimination of gravid tapeworm segments (*Moniezia* spp).

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active substance 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 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.

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.

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.

4.5 Special precautions for use

Special precautions for use in animals

When a dosing gun is used to administer the product, care must be taken to avoid damage to the pharyngeal region.

Adverse effects (see section 4.6) are occasionally enhanced in animals suffering from severe liver damage and/or dehydration at the time of dosing.

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.

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.

4.6 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.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy or lactation. See section 4.5.

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Oral Use. Shake 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

4.10 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.

4.11 Withdrawal period

Cattle:

Meat and offal: 13 days.

Milk: 108 hours (4.5 days).

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Oxyclozanide

ATCvet code: QP52AG06.

5.1 Pharmacodynamic properties

Oxyclozanide is an anthelmintic of the salicylanilide group. The salicylanilides are proton ionophores, which act as specific uncouplers of mitochondrial oxidative phosphorylation, disrupting the metabolism of the parasite. The chemical structure of salicylanilides is characterised by the presence of an unstable proton. They are lipophilic molecules which allow the passage of protons across membranes, especially through the inner mitochondrial membrane.
Oxyclozanide has flukicidal activity against the adult stage of *Fasciola hepatica*. Its efficacy against cestodes is limited to the removal of segments of the tapeworm *Moniezia.*

5.2 Pharmacokinetic properties

Oxyclozanide is slowly absorbed after oral administration with peak plasma levels approximately 11 hours after dosing. After oral administration of the product to cattle at a dose rate of 10 mg oxyclozanide per kg bodyweight the following parameters were observed: C_{max} of 9.1 µg/ml, t½ of 11.3 hours and AUC of 231.0 µg.h/ml. 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.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate
Sodium laurilsulfate
Propylene Glycol

Sodium Citrate
Disodium Edetate
Carmellose Sodium
Aluminium Magnesium Silicate
Simeticone
Purified Water

6.2 Major 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: 3 years.
Shelf life after first opening the immediate packaging: 1 year.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

1L, 2.5L & 5L: White High Density Polyethylene HDPE flexi containers with a 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.

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

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.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8. MARKETING AUTHORISATION NUMBER

Vm 08749/4077

9. DATE OF FIRST AUTHORISATION

26 August 2016

10. DATE OF REVISION OF THE TEXT

May 2021

Approved: 06/05/21