1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Oxyclozanide 34.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl Parahydroxybenzoate (E218)	2.0 mg
Propyl Parahydroxybenzoate	0.2 mg
Sodium laurilsulfate	-
Propylene Glycol	-
Sodium Citrate	-
Disodium Edetate	-
Carmellose Sodium	-
Aluminium Magnesium Silicate	-
Simeticone	-
Purified Water	-

A smooth uniform off-white to yellow suspension.

3. CLINICAL INORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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

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

3.3 Contraindications

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

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 3.6) 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.

Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product.

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.

Special precautions for the protection of the environment:

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.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data)	Loose stool Diarrhoea Inappetence [1] Milk production decrease [2]

[1] Transient.

[2] 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy, lactation and fertility:

Can be used during pregnancy or lactation. See section 3.5.

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral Use. Shake well before use.

To ensure a correct dosage, 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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal period

Cattle:

Meat and offal: 13 days.

Milk: 108 hours (4.5 days).

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AG06

4.2 Pharmacodynamics

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.*

4.3 Pharmacokinetics

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).

4.4 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

1 L, 2.5 L & 5 L: 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.

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

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as Oxyclozanide may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to veterinary prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

{ Carton for 1 L, 2.5 L, 5 L and 10 L}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

2. COMPOSITION

Each ml contains:

Active substance:

Oxyclozanide	34.0 mg/ml

Excipients:

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

3. PACKAGE SIZE

1 L, 2.5 L, 5 L, 10 L

Not all pack sizes may be marketed.

4. TARGET SPECIES

Cattle.

5. INDICATIONS FOR USE

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

Special Warnings:

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.

Special precautions for safe use in the target species:
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. Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product.
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.

Special precautions for the protection of the environment:
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.

Pregnancy, lactation and fertility:

Can be used during pregnancy or lactation. Special precautions for safe use in the target species.
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:

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.

8. ADVERSE EVENTS

Adverse events

Cattle

Undetermined frequency (cannot be estimated from the available data)	Loose stool Diarrhoea Inappetence [1] Milk production decrease [2]

[1] transient.

[2] 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.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system. {national system details}

9. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Oral Use.

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

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Shake the product well before use.

To ensure a correct dosage, 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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 13 days.

Milk: 108 hours (4.5 days).

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as Oxyclozanide may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to veterinary prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes: 1 L, 2.5 L, 5 L, 10 L.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.

Loughrea

Co. Galway

Ireland

Local representatives and contact details to report suspected adverse events:

18. OTHER INFORMATION

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.

The product can be marketed with or without an outer carton.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 12 months.

Once opened, use by _____

21. BATCH NUMBER

Lot {number}

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

{ Label for 1 L, 2.5 L, 5 L and 10 L}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

2. COMPOSITION

Each ml contains:

Active substance:

Oxyclozanide	34.0 mg/ml

Excipients:

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

3. PACKAGE SIZE

1 L, 2.5 L, 5 L, 10 L

Not all pack sizes may be marketed.

4. TARGET SPECIES

Cattle.

5. INDICATIONS FOR USE

Indications for use

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

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

Treats adult liver fluke tapeworm.

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

Special Warnings:

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.

Special precautions for safe use in the target species:

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. Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product.

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.

Special precautions for the protection of the environment:

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.

Pregnancy, lactation and fertility:

Can be used during pregnancy or lactation. Special precautions for safe use in the target species.
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:

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.

8. ADVERSE EVENTS

Adverse events

Cattle

Undetermined frequency (cannot be estimated from the available data)	Loose stool Diarrhoea Inappetence [1] Milk production decrease [2]

[1] Transient.

[2] 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.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system. {national system details}

9. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Oral Use.

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

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Shake the product well before use.

To ensure a correct dosage, 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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 13 days.

Milk: 108 hours (4.5 days).

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as Oxyclozanide may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to veterinary prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes: 1 L, 2.5 L, 5 L, 10 L.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.

Loughrea

Co. Galway

Ireland

Local representatives and contact details to report suspected adverse events:

18. OTHER INFORMATION

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.

The product can be marketed with or without an outer carton.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 12 months.

Once opened, use by _____

21. BATCH NUMBER

Lot {number}