LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 litre / 2.5 litre / 5 litre Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxyfluke 34 mg/ml Oral Suspension for Cattle and Sheep
Oxyclozanide

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

1 L
2.5 L
5 L
2 x 5 L

5. TARGET SPECIES

Cattle and Sheep

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

To be included on product cartons where font size considerations permit

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

8. WITHDRAWAL PERIOD

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

Sheep
Meat and offal: 14 days
Milk: 7 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP dd/mm/yyyy
Once opened use within: 6 months.

11. SPECIAL STORAGE CONDITIONS

Protect from light.

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

Disposal: Read package leaflet

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

For animal treatment only.
<Supply category to be completed nationally>

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

Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4422

17. MANUFACTURER'S BATCH NUMBER

BN

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL

1 litre / 2.5 litre / 5 litre label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxyfluke 34 mg/ml Oral Suspension for Cattle and Sheep
Oxyclozanide

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

1 L
2.5 L
5 L

5. TARGET SPECIES

Cattle and Sheep

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle
Meat and offal: 13 days

Milk: 108 hours (4.5 days)

Sheep
Meat and offal: 14 days
Milk: 7 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP dd/mm/yyyy
Once opened use within: 6 months.

11. SPECIAL STORAGE CONDITIONS

Protect from light.

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

Disposal: Read package leaflet

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

For animal treatment only.
<Supply category – to be completed nationally>

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

Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4422

17. MANUFACTURER'S BATCH NUMBER

BN

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Oxyfluke 34 mg/ml Oral Suspension for Cattle and Sheep

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

Marketing Authorisation Holder and manufacturer responsible for batch release:
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxyfluke 34 mg/ml Oral Suspension for Cattle and Sheep
Oxyclozanide

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

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

An off white to beige suspension.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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.

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

7. TARGET SPECIES

Cattle and Sheep

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

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

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

9. ADVICE ON CORRECT ADMINISTRATION

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.

Follow the applicator gun manufacturer’s directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

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.

10. WITHDRAWAL PERIOD

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

Sheep
Meat and offal: 14 days
Milk: 7 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP.
Shelf life after first opening the container: 6 months

12. SPECIAL WARNINGS

Special precautions for use in animals:
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 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 trematodes and recommendations on how to limit further selection for resistance to anthelmintics.

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
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.

Pregnancy, Lactation and Lay:
The product can be used in pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2019

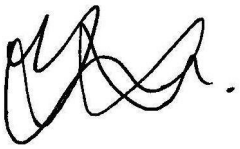
15. OTHER INFORMATION

The product is available in the following packs:

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.



Approved: 26 April 2022