LABELLING AND PACKAGE LEAFLET

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

LABEL

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder and manufacturer responsible for batch release:
Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

2. Name of the veterinary medicinal product

Flukanide 30 mg/ml oral suspension for sheep
Rafoxanide

3. Statement of the active substance and other ingredients

Each ml of product contains:

Active substance:	
Rafoxanide	30.00 mg
Excipients:	
Tartrazine yellow (E102)	0.07 mg
Propyl parahydroxybenzoate (E216)	0.20 mg
Methyl parahydroxybenzoate (E218)	2.00 mg

A yellow suspension.

4. Pharmaceutical form

Oral suspension.

5. Package size

1L
2.5L
5L

6. Indications

For the treatment of mature liver fluke infections (*Fasciola hepatica*).

7. Contraindications

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

8. Adverse reactions

None.

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

9. Target species

Sheep

10. Dosage for each species, route and method of administration

For oral administration.

To be given orally at a dose of 11.25 mg rafoxanide per kg bodyweight equivalent to 3 ml of product per 8 kg bodyweight.

11. Advice on correct administration

Accuracy of the dosing device should be checked.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

12. Withdrawal period

Withdrawal period:
Meat: 78 days
Milk: Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

13. Special storage precautions

Do not freeze.
Following withdrawal of the first dose, use the product within 3 months.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.

14. Special warning(s)

Special warnings for each target species:
Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual flock.

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 bodyweight, mis-administration of the product or lack of calibration of the dosing device.

Resistance to rafoxanide has been reported in immature 6-week-old *Fasciola hepatica* in artificially infected sheep in Australia (1989). In the study, two isolates of *Fasciola hepatica* that were resistant to rafoxanide were also resistant to closantel (another salicylanilide), indicating possible side resistance. However, the fluke isolates resistant to rafoxanide and closantel did not demonstrate side resistance to the salicylanilide oxyclozanide.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to rafoxanide or any of the listed excipients should avoid contact with the veterinary medicinal product.
Do not eat, drink or smoke while handling the product.
Wash hands and exposed skin before meals and after work.
If accidental contact with the skin or eyes occurs, wash off any skin contamination with soap and water immediately. Rinse the affected eyes thoroughly with clean, fresh water. Remove any contaminated clothing immediately.

Environmental precautions
Rafoxanide is very toxic to dung insects. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore, the product must only be administered once per year to affected animals only.

Pregnancy:
Can be used during pregnancy.

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

Overdose (symptoms, emergency procedures, antidotes):
No specific signs.

Incompatibilities:
None known.

15. Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Rafoxanide should not enter water courses as this may be dangerous for fish and other aquatic organisms.

16. Date on which the label was last approved

April 2023

17. Other information

Pack sizes:
1 litre container
2.5 litre container
5 litre container
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. To be supplied only on veterinary prescription. POM-V

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}

21. Marketing authorisation number

Vm 05150/4009

22. Manufacturer’s batch number

<Batch> <Lot> <BN> {number}

OPTIONAL LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND THE IMMEDIATE PACKAGE

LABEL/CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukanide 30 mg/ml oral suspension for sheep
Rafoxanide

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 30 mg of rafoxanide.

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

1L
2.5L
5L

5. TARGET SPECIES

Sheep.

6. INDICATIONS

For the treatment and control of fluke infections in sheep.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.
For oral administration.
To be given orally at a dose of 11.25 mg rafoxanide per kg bodyweight equivalent to 3 ml of product per 8 kg bodyweight.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat: 78 days
Milk: Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not freeze.
Following withdrawal of the first dose, use the product within 3 months.

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. To be supplied only on veterinary prescription. POM-V

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

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05150/4009

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

PACKAGE LEAFLET:
Flukanide 30 mg/ml oral suspension for sheep

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

Marketing authorisation holder and manufacturer responsible for batch release:

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukanide 30 mg/ml oral suspension for sheep
Rafoxanide

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:	
Rafoxanide	30.00 mg
Excipients:	
Tartrazine yellow (E102)	0.07 mg
Propyl parahydroxybenzoate (E216)	0.20 mg
Methyl parahydroxybenzoate (E218)	2.00 mg

4. INDICATION(S)

For the treatment of mature liver fluke infections (*Fasciola hepatica*).

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None.

7. TARGET SPECIES

Sheep

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.

To be given orally at a dose of 11.25 mg rafoxanide per kg bodyweight equivalent to 3 ml of product per 8 kg bodyweight.

Accuracy of the dosing device should be checked.

Underdosing could result in ineffective use and may favour resistance development.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

10. WITHDRAWAL PERIOD(S)

Meat: 78days
Milk: Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Following withdrawal of the first dose, use the product within 3 months.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual flock.

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Resistance to rafoxanide has been reported in immature 6-week-old *Fasciola hepatica* in artificially infected sheep in Australia (1989). In the study, two isolates of *Fasciola hepatica* that were resistant to rafoxanide were also resistant to closantel (another salicylanilide), indicating possible side resistance. However, the fluke isolates resistant to rafoxanide and closantel did not demonstrate side resistance to the salicylanilide oxyclozanide.

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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

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.

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

This product may be irritating to skin and eyes or cause hypersensitivity. People with known hypersensitivity to rafoxanide or any of the listed excipients should avoid contact with the product. Wear nitrile rubber gloves when applying the product. Do not eat, drink, or smoke while handling the product. If accidental contact with the skin or eyes occurs, wash off any skin contamination with soap and water immediately. Rinse the affected eyes thoroughly with clean, fresh water. Remove and wash any contaminated clothing immediately. Wash hands after use.

Environmental precautions

Rafoxanide is very toxic to dung insects. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore, the product must only be administered once per year to affected animals only.

Pregnancy:

Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:

None known

Overdose (symptoms, emergency procedures, antidotes):

No specific signs.

Incompatibilities:

None known

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

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Rafoxanide should not enter water courses as this may be dangerous for fish and other aquatic organisms.

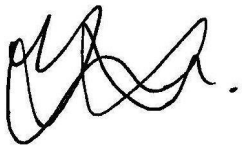
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2023

15. OTHER INFORMATION

Not all pack sizes may be marketed.
This product may be marketed with or without an outer carton.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 19 April 2023