

LABELLING AND PACKAGE LEAFLET

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

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukanide 30 mg/ml oral suspension for sheep

2. COMPOSITION

Each ml contains:

Active substance:

Rafoxanide 30.00 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Tartrazine yellow (E102)	0.07 mg
Propyl parahydroxybenzoate (E216)	0.20 mg
Methyl parahydroxybenzoate (E218)	2.00 mg

A yellow suspension.

3. PACKAGE SIZE

1L
2.5L
5L

4. TARGET SPECIES

Sheep.

5. INDICATIONS FOR USE

Indications for use

For the treatment of liver fluke (*Fasciola hepatica*) infections (6-8 week immature and adult).

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:

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.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific flock should be sought from the responsible veterinarian.

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 oxclozanide.

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 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.

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.

Special precautions for the protection of the environment:

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:

No specific signs.

Major incompatibilities:

None known.

8. ADVERSE EVENTS

Adverse events

None.

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Dosage for each species, routes and method of administration

For single 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.

10. ADVICE ON CORRECT ADMINISTRATION

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 farm history, and where appropriate, supported by diagnostic testing, 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.

11. WITHDRAWAL PERIODS

Withdrawal periods:

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.

12. SPECIAL STORAGE PRECAUTIONS

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

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.

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

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 05150/4009

Pack sizes

1L
2.5L
5L

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Univet Limited
Tullyvin
Cootehill
County Cavan
Ireland
Tel: +353 49-5553203

18. OTHER INFORMATION

Other information

POM-VPS

Rafoxanide is very persistent in soils.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once broached use by...

Shelf life after first opening the immediate packaging: 3 months

21. BATCH NUMBER

Lot {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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 30 mg of rafoxanide.

3. PACKAGE SIZE

1L
2.5L
5L

4. TARGET SPECIES

Sheep.

5. INDICATIONS

For the treatment of liver fluke (*Fasciola hepatica*) infections (6-8 week immature and adult).

6. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE CONDITIONS

Do not freeze.

Following withdrawal of the first dose, use the product within 3 months.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

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

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 05150/4009

15. BATCH NUMBER

Lot {number}

16. OTHER INFORMATION

For single oral administration, at a dose of 11.25 mg rafoxanide per kg bodyweight equivalent to 3 ml of product per 8 kg bodyweight.

The product must only be administered once per year to affected animals only.

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Overdose:

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Major incompatibilities:

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7. Adverse events

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14. Marketing authorisation numbers and pack sizes

Vm 05150/4009

Pack sizes

1L

2.5L

5L

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This product may be marketed with or without an outer carton.

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Cootehill
County Cavan
H16 T183
Ireland
Tel: + 353 49-5553203

17. Other information

POM-VPS

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Gavin Hall

Approved: 18 March 2026