1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curafluke 50 mg/ml oral drench for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substances:

Fenbendazole 50.00 mg
Rafoxanide 50.00 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Propyl parahydroxybenzoate	0.10 mg
Methyl parahydroxybenzoate	1.00 mg
Quinoline yellow	0.09 mg
Xanthan gum (E415)	
Simethicone emulsion	
Polysorbate 80	
Sodium citrate (E331)	
Sodium metabisulphite (E223)	
Citric acid monohydrate	
Purified water	

A pale, lemon oral suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

The veterinary medicinal product permits a three way activity against fluke, lungworms and stomach worms in cattle and sheep. It is a broad spectrum anthelmintic for the treatment of benzimidazole susceptible mature and immature stages of nematodes and cestodes of the gastrointestinal and respiratory tracts of cattle and sheep. Rafoxanide is active against immature and mature Fasciola hepatica (mature and immature over 8 weeks of age).

Haemonchus spp.
Ostertagia spp.
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Bunostomum spp.

Trichuris spp.
Strongyloides spp.
Oesophagostomum spp.
Dictyocaulus spp.
Moniezia spp.
Fasciola hepatica (mature and immature over 8 weeks of age).

The veterinary medicinal product has a good therapeutic effect against type II Ostertagiasis.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 under-estimation of the bodyweight, mis-administration of the product or lack of calibration of the dosing device (if any).

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 on anthelmintics resistance developing. If the product does not achieve the desired clinical effect, other diseases, nutritional diseases or anthelmintic resistance may be involved.

Where a dosing gun is used to administer the product care must be taken to avoid the occurrence of dosing gun pharyngitis.

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

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy.
Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.
Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral use.
For sheep, the recommended therapeutic dose is 7.5 mg fenbendazole and 7.5 mg rafoxanide per kilogram bodyweight.
For cattle, the recommended therapeutic dose is 11.25 mg fenbendazole and 11.25 mg rafoxanide per kilogram bodyweight.
Shake well before use.
To ensure a correct dosage, body weight should be determined as accurately as possible.
Use only properly calibrated dosing equipment.
Practical dosage recommendations are as follows:

Cattle:

Bodyweight (Kg)	Dose (ml)
50	11.25
100	22.5
400	90.0
>400	11.25 ml/50 kg

Sheep:

Bodyweight (Kg)	Dose (ml)
10	1.5
50	7.5

At 2 months after housing, when dosing cattle for worms and adult fluke, a lower dose of 7.5 mg/kg can be used i.e. 7.5 ml per 50 kg bodyweight, 30 ml per 200 kg or 75 ml per 500 kg.

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

The veterinary medicinal product is well tolerated in cattle at three times the recommended dosage.

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 periods

Meat and offal:
Cattle - 60 days.
Sheep - 54 days.

Milk: Not authorised for use in animals producing milk for human consumption including during the dry period. Do not use during the last trimester of pregnancy in heifers which are intended to produce

milk for human consumption. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP52AC30

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from light.
Protect from frost.

5.4 Nature and composition of immediate packaging

1 L (jerrican, backpack), 2.5 L (jerrican, backpack) or 5 L (jerrican, backpack) HDPE white rigid containers with a polypropylene screw cap and an induction heat seal liner.

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.

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

Univet Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/032/001

8. DATE OF FIRST AUTHORISATION

05/09/1997

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

10/10/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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