1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Triazole fluke and worm drench for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Levamisole hydrochloride 15 mg
Rafoxanide 22.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium metabisulphite (E223)	0.5 mg
Propyl parahydroxybenzoate (E216)	0.1 mg
Methyl parahydroxybenzoate (E218)	1.0 mg
Quinoline yellow (E104)	0.09 mg
Polysorbate 80	
Sodium citrate	
Citric acid monohydrate	
Xanthan gum	
Simethicone emulsion	
Purified water	

A yellow aqueous 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 is a combination product for the treatment of the common nematode parasites (including lung worm - *Dictyocaulus* spp.) and liver fluke (*Fasciola hepatica)* of cattle and sheep.

The veterinary medicinal product is active against:
Fasciola hepatica (mature and immature over 8 weeks of age)
Nematodirus spp.
Dictyocaulus spp.
Ostertagia spp. (except inhibited ostertagia larvae)

3.3 Contraindications

Do not use in concurrent treatment with organophosphates and / or diethylcarbamazine.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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, misadministration of the veterinary medicinal product, or lack of calibration of the dosing device.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Shake well before use.
When a dosing gun is used to administer the veterinary medicinal product, care should be taken to avoid injury to the mouth and pharynx.

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

Wash hands after use.
Wash splashes from eyes and hands immediately.
Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using the veterinary medicinal product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle and sheep:

Undetermined frequency (cannot be estimated from the available data):	Liver disorder[1]

[1] May have occurred before treatment is given. Can lead to death in severe cases.

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Treatment with organophosphates and / or diethylcarbamazine within 14 days of treatment with the veterinary medicinal product is contraindicated.

3.9 Administration routes and dosage

Oral use.
To be given at a dose rate of 7.5 mg levamisole HCl/kg bodyweight & 11.25 mg rafoxanide/kg bodyweight. Shake well before use.

To ensure a correct dosage, bodyweight 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.
The veterinary surgeon should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control.

Practical dosage recommendations are as follows:

Cattle	**Sheep**
50 kg - 25 ml	15 kg - 5 ml
100 kg - 50 ml	25 kg - 10 ml
150 kg - 75 ml	35 kg - 15 ml
200 kg - 100 ml	40 kg - 20 ml
250 kg - 125 ml	
300 kg - 150 ml	

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

Accidental overdosage - animals may become hyperactive and excitable, with head shaking, salivation and muscle twitching. These effects are transient.

Rafoxanide is a particularly safe drug even at dose rates substantially above those normally recommended. The recommended dose rate is 11.25 mg/kg. At 33.75 mg/kg, as used in the tolerance trials, there was no clinical or biochemical evidence of toxic effects, even when combined with levamisole.

On the basis of the available information, it is clear that while levamisole does not have the safety index of some of the alternative anthelmintics (e.g. the benzimidazoles), its safety is adequate given careful usage and reasonably accurate weight estimation in domestic ruminants. This point is raised on the label and package insert. Its field usage over the years since its first introduction supports this conclusion. Furthermore, where toxic signs have occurred at dose levels two to three times over the recommended level, the signs have been transient with the vast majority of animals showing signs recovering in a few hours at most.

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

Cattle:
Meat and offal: 60 days.
Milk: Not authorised for use in cattle producing milk for human consumption, including pregnant cattle intended to produce milk for human consumption.

Sheep:
Meat and offal: 60 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP52AE51

4.2 Pharmacodynamics

The veterinary medicinal product is a combination product containing the anthelmintic, levamisole HCl, and the flukicide, rafoxanide.

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 ºC.
Do not freeze.

5.4 Nature and composition of immediate packaging

2.5 L, 5 L HDPE white rigid containers closed with a polypropylene screw cap with 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

Pharvet (Ireland) Ltd.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10462/001/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

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

24/09/2026

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).