Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Triazole Fluke and Worm Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances

Levamisole Hydrochloride	15 mg
Rafoxanide	22.5 mg

Excipients

Sodium Metabisulphite (E223)	0.5 mg
Propyl Parahydroxybenzoate(E216)	0.1 mg
Methyl Parahydroxybenzoate(E218)	1.0 mg
Quinoline Yellow (E104)	0.09 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension
A yellow aqueous oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

Triazole 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.

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

4.3 Contraindications

Do not use in concurrent treatment with organophosphates and / or diethylcarbamazine.
Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each 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 underestimation of bodyweight, misadministration of the 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.

4.5 Special precautions for use

Special precautions for use in animals

Shake well before use.
When a dosing gun is used to administer the 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 product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

Irreversible liver damage may have occurred before treatment is given. This can lead to death in severe cases irrespective of treatment.

4.7 Use during pregnancy, lactation or lay

See section 4.11

4.8 Interaction with other medicinal products and other forms of interaction

Treatment with organophosphates and / or diethylcarbamazine within 14 days of treatment with Triazole is contraindicated.

4.9 Amounts to be administered and administration route

To be given orally at a dose rate of 7.5 mg Levamisole HCl/kg bodyweight & 11.25 mg Rafoxanide/kg bodyweight. Shake well before use.

To ensure administration of a correct dose, 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 to	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	

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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-¹. At 33.75 mg.kg-¹, 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 ocurred 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.

4.11Withdrawal Period(s)

Animals should not be slaughtered for human consumption during treatment or for 60 days thereafter.
Cattle: Not authorised for use in cattle producing milk for human consumption, including pregnant cattle intended to produce milk for human consumption.
Sheep: 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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, levamisole, combinations
ATCvet code: QP52AE51

5.1 Pharmacodynamic properties

Triazole Fluke and Worm Drench is a combination product containing the anthelmintic, levamisole HCl, and the flukicide, rafoxanide.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite (E223)
Polysorbate 80
Propyl Parahydroxybenzoate (E216)
Methyl Parahydroxybenzoate (E218)
Quinoline Yellow (E104)
Sodium Citrate
Citric Acid Monohydrate
Xanthan Gum
Simethicone emulsion
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Store below 25ºC.
Do not freeze.

6.5 Nature and composition of immediate packaging

2.5L, 5L HDPE white rigid containers closed with a polypropylene screw cap with an induction heat seal liner.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Pharvet (Ireland) Ltd.,
29 Cookstown Industrial Estate,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10462/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009.

10 DATE OF REVISION OF THE TEXT

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