

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fluken Worm Oral Drench.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances

Levamisole Hydrochloride	15.0 mg
Rafoxanide	22.5 mg

Excipients

Methyl Parahydroxybenzoate	1.0 mg
Propyl Parahydroxybenzoate	0.1 mg
Sodium Metabisulphite	0.5 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 suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep

4.2 Indications for use, specifying the target species

Fluken Worm Oral Drench is a combination product for the treatment of the common nematode parasites of cattle and sheep (including lung worm – *Dictyocaulus* spp.) and the liver fluke (*Fasciola hepatica*).

Fluken Worm Oral Drench is active against:

Fasciola hepatica (mature and immature larvae over 8 weeks of age),

Nematodirus sp.,

Dictyocaulus sp.,

Ostertagia sp., (except inhibited ostertagia larvae in cattle)

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

Carefully estimate the live weight of animals.
 Use only properly calibrated dosing equipment.
 Frequent and repeated use of anthelmintics from the same class over an extended period of time might lead to an increased risk of development of resistance to anthelmintic drugs. To reduce this risk, dosing programs should be discussed with your veterinary surgeon.

4.5 Special precautions for use

Special precautions for use in animals

When a dosing gun is used to administer the product, care should be taken to avoid dosing gun pharyngitis.

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

Shake well before use.
 Wash splashes from eyes and hands 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

Concurrent treatment with organophosphates and/or diethylcarbamazine within 14 days of treatment with Fluken Worm Oral Drench is contraindicated.

4.9 Amounts to be administered and administration route

To be given orally at a dose rate of 7.5 mg/kg bodyweight for Levamisole Hcl and 11.25 mg/kg bodyweight for Rafoxanide.
 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	

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 and at this dose rate and even at 33.75 mg/kg as used in the tolerance trials, there was no clinical or biochemical evidence of toxic effect, 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.

4.11 Withdrawal Period(s)

Cattle and sheep must 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.

ATCvet code: QP52A

5.1 Pharmacodynamic properties

Fluken Worm Oral Drench is a combination product containing the anthelmintic, Levamisole HCl, and the flukicide Rafoxanide.

Rafoxanide

Rafoxanide is one of a group of halogenated salicylanilides with the chemical formula 3'-chloro-4'-(p-chlorophenoxy)-3, 5-diiodosalicylanilide

Levamisole HCl

Levamisole, the second active ingredient of the product, is given as (-)-2,3,5,6-tetrahydro-6-phenylimidazo(2,1-b)thiazole.

Fulken Worm Oral Drench is a combination product for the treatment of the common nematode parasites (levamisole) of cattle and sheep (including lung worm – *Dictyocaulus* spp.) and the liver fluke (*Fasciola hepatica* – rafoxanide). The two actives are both effective anthelmintics in their own right and are used in other combined products.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite
Polysorbate 80
Propyl Parahydroxybenzoate
Methyl Parahydroxybenzoate
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

Do not store above 25°C.
Do not freeze.

6.5 Nature and composition of immediate packaging

A suspension in 2.5L (jerrican) and 5L (jerrican) HDPE white rigid containers, closed with a HDPP screw cap with a wood pulp PVDC liner.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Quinn's Chemist,
Bridge Street,
Crossmolina,
Co. Mayo.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10813/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th December 2008

10 DATE OF REVISION OF THE TEXT

April 2013