1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zanil Fluke Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance		
Oxyclozanide	3.4	% w/v
Excipients		
Methyl Parahydroxybenzoate E218	0.15	% w/v
Propyl Parahydroxybenzoate E216	0.015	% w/v
Sodium Metabisulphite E223		
Sodium Citrate E331		

3 PHARMACEUTICAL FORM

Oral suspension.
A smooth off-white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep.

4.2 Indications for use, specifying the target species

Indications: For the treatment and control of fascioliasis in cattle and sheep.

It removes practically all adult flukes (*Fasciola* spp.) present in the bile ducts of the liver. Tapeworm segments (*Moniezia*) are also removed.

4.3 Contraindications

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

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 body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

  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 test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

  Milking cattle, particularly high yielders, may show a reduction in yield, occasionally of 5 % or more, for about 48 hours after handling.The effect of this small loss may be minimised byspreading herd dosing over a period of about one week.

4.5 Special precautions for use

Special precaution(s) for use in animals

Care should be taken when administering by dosing gun.

Due regard must always be given to the physical condition of animals undergoing treatment, particularly those in advanced pregnancy and/or under stress from adverse weather conditions, poor nutrition, penning, handling etc.

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

When using, do not eat, drink or smoke.
Wash splashes immediately from eyes and skin immediately.
Take off any contaminated clothing immediately.
Wash hands and exposed skin before meals and after work.

4.6 Adverse reactions (frequency and seriousness)

At normal oxyclozanide dose levels, cattle may show slight softening of the faeces with the occasional animal showing increased frequency of defaecation and transient inappetence.

These effects are occasionally enhanced in animals suffering from severe liver damage and/or dehydration at the time of dosing.

4.7 Use during pregnancy, lactation or lay

The product may be given to pregnant and lactating animals.However, due regard must always be given to physical condition, particularly of any animals in advanced

pregnancy, and/or under stress from adverse weather conditions, poor nutrition, penning, handling etc.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Give as an oral drench. Shake the product well before use.

To ensure administration of a correct dose, body weight 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.

Dose according to bodyweight at the rate of 10 mg oxyclozanide per kg bodyweight (cattle) and 15 mg oxyclozanide per kg bodyweight (sheep).

Cattle: 3 ml per 10 kg bodyweight;

For example:

Bodyweight Dose
50 kg (approx 1 cwt) 15 ml
100 kg (approx 2 cwt) 30 ml
150 kg (approx 3 cwt) 45 ml
200 kg (approx 4 cwt) 60 ml
250 kg (approx 5 cwt) 75 ml
300 kg (approx 6 cwt) 90 ml
350 kg and over (7 cwt and over) 105 ml

Drench can be given in the feed to cattle which are fed individually. Pour the recommended dose onto their concentrate ration. Molasses or salt may be added for shy feeders.

Sheep: 4.5 ml per 10 kg bodyweightFor example:

Bodyweight Dose
10 kg (approx 22 lb) 4.5 ml
20 kg (approx 44 lb) 9 ml
30 kg (approx 66 lb) 13.5 ml
40 kg (approx 88 lb) 18 ml
45 kg and over (approx. 100 lb and over) 20 ml

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

The effects of oxyclozanide overdosage are dullness and some loosening of faeces in sheep and possible diarrhoea, inappetence and loss of weight in cattle.These effects are occasionally enhanced in animals with severe liver damage and/or dehydration at the time of dosing.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 13 days.
Milk: 108 hours (4.5 days).

Sheep:
Meat and offal: 14 days.
Milk: 7 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Oxyclozanide
ATCvet code: QP52AG06.

5.1 Pharmacodynamic properties

Oxyclozanide is a salicylanide anthelmintic. The mechanism of action is by uncoupling of oxidative phosphorylation in liver fluke.

5.2 Pharmacokinetic particulars

Oxyclozanide is slowly absorbed after oral administration with peak plasma levels 24 hours after dosing.Excretion is predominantly faecal, biliary excretion being the most important route of elimination (cattle studies only).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Laurilsulphate
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Aluminium Magnesium Silicate
Carmellose Sodium
Sodium Metabisulphite (E223)
Sodium Citrate Purified Water

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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 25°C.
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

High density polyethylene bottles of 1, 2.5, 5 and 10 litre nominal volume, and high density polyethylene back-packs of 1, 2.5 and 5 litre nominal volume.
Closure: Polypropylene or urea formaldehyde screw cap with wads of PVDC-faced paper on a pulpboard liner.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.
Do not contaminate ponds, waterways or ditches.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10996/262/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of latest renewal: 12th November 2010

10 DATE OF REVISION OF THE TEXT

November 2017