IRISH MEDICINES BOARD ACT 1995, as amended

European Communities (Animal Remedies) (No. 2) Regulations 2007

VPA: **10990/027/002**
Case No: 7007721

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Univet Limited

Tullyvin, **Cootehill**, **Co. Cavan.**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Flukex 9% w/v Oral Drench

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation,unless revoked, shall continue in force from **06/08/2010**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flukex 9% w/v Oral Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance		
Rafoxanide	90	mg
Excipients		
Quinoline Yellow E104	0.09	mg
Propyl Porahydroxybenzoate E216	0.1	mg
Methyl Parahydroxybenxoate E218	1.0	mg
Sodium Metabisulphite E223	0.5	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
A yellow suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For the treatment and control of mature and immature fluke over 8-weeks of age in cattle.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the product.

4.4 Special warnings for each target species

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

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

Where a dosing gun is used to administer the product, care must be taken to avoid injury to the mouth or pharynx.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Rafoxanide is safe for use during pregnancy. However, the product is not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

The product should not be diluted or mixed with any other products before administration.

4.9 Amounts to be administered and administration route

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.

To be given orally to cattle at a dose rate of 11.25 mg/kg bodyweight for cattle.
Practical dosage recommendations are as follows:

Cattle

50	kg -	6.25 ml
100	kg -	12.50 ml
150	kg -	18.75 ml
200	kg -	25.00 ml
250	kg -	31.25 ml
300	kg -	37.50 ml
400	kg -	50.00 ml
500	kg -	62.50 ml

The dose for heavier cattle is an additional 6.25ml per 50kg.

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

The product is tolerated at three times the recommended dosage in the target species.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment or for 60 days thereafter.
Milk:
Not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, salicylanilides
ATCvet code: QP52AG05

5.1 Pharmacodynamic properties

Summary presentation of the active ingredients

Rafoxanide (QP52AG05) is a salicylanilide anthelmintic and these are known to be potent uncouplers of oxidative phosphorylation in animal tissues.

In vitro experiments indicate that salicylanilides, including the commercially used flukicide, rafoxanide, uncouples oxidative phosphorylation in *Fasciola hepatica* and other parasites.

5.2 Pharmacokinetic properties

Kinetic studies of rafoxanide in cattle have shown that it is absorbed into the blood with a mean peak concentration of *circa* 23 µg.ml^{-1} achieved in 2 to 3 days. Plasma are considerably higher than those in tissues. Only one metabolite has been identified (3, 5-di-iodosalicylic acid) and this was found in blood tissues and milk. There is little known or reported on the excretion of rafoxanide though apparently it is excreted in the bile.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

1 L, 2.5 L and 5L HDPE white rigid containers closed with a 38 mm HDPE 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 veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Univet Ltd.
Tullyvin
Cootehill
County Cavan

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/027/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th August 2010

10 DATE OF REVISION OF THE TEXT