IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10555/002/001**
Case No: 7007746

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:

Interchem Ireland Ltd

Road M, Unit 12, **Tougher Business Park, Newhall**, **Naas, Co. Kildare**, **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:

Flukinex 9% w/v Oral Suspension

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **27/04/2010**.

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

Flukinex 9% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	per ml
Active Substance	
Rafoxanide	90 mg
Excipients	
Quinoline Yellow (E104)	0.09 mg
Propyl Parahydroxybenzoate (E216)	0.10 mg
Methyl Parahydroxybenzoate (E218)	1.00 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.

A yellow free flowing suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For the treatment 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 occured before treatment is given. This can lead to death in severe cases irrespective of treatment.

4.5 Special precautions for use

Special precautions for use in animals
When a dosing gun is used to administer the product, care must be taken to avoid the occurrence of dosing gun pharyngitis.

Special precautions to be taken by the person administering the product to animals
Wash hands after use.
Wash splashes from eyes and hands immediately.

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

Flukinex 9% should not be diluted or mixed with other products before administration.

4.9 Amounts to be administered and administration route

For oral administration in cattle.
The recommended therapeutic dose is 11.25 mg rafoxanide per kilogram bodyweight.

Shake well before use.
Estimate bodyweight carefully.
Use only properly calibrated dosing equipment.
Practical dosage recommendations are as follows:

Cattle

Bodyweight (kg)	Dose (ml)
50	6.25
100	12.50
150	18.75
200	25.00
250	31.25
300	37.50
400	50.00
500	62.50

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

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

Flukinex 9% is well tolerated in cattle at three times the recommended dosage.

4.11 Withdrawal Period(s)

Meat and offal
Cattle: 60 days.

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

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.

5.1 Pharmacodynamic properties

*In vitr*o experiments indicate that salicylanilides, including rafoxanide, uncouple 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 microgram.ml^{-1} achieved in 2 to 3 days. Plasma aconcentrations 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

Quinoline Yellow (E104)
Propyl Parahydroxybenzoate (E216)
Methyl Parahydroxybenzoate (E218)
Xanthan Gum (E415)
Simeticone
Polysorbate 80
Sodium Citrate (E331)
Sodium Metabisulphite (E223)
Citric Acid Monohydrate
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Two years.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Store in the original container in order to protect from light.
Protect from freezing.

6.5 Nature and composition of immediate packaging

1 L, 2.5 L, 5 L HDPE white rigid containers closed with a 38 mm HDPP screw cap with a wood pulp PVDC liner.

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

Interchem (Ireland) Ltd.,
Road M,
Unit 12,
Tougher Business Park,
Newhall,
Naas,
Co. Kildare.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10555/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th June 2006

10 DATE OF REVISION OF THE TEXT

12th February 2010