IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/036/001**
Case No: 7007671

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:

Intervet Ireland Limited

Magna Drive, **Magna Business Park**, **Dublin 24**, **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:

Deldrax 340 mg/ml Solution for Injection

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 **28/04/2010**.

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

Deldrax 340 mg/ml Solution for injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Nitroxynil as N-ethylglucamine salt	340 mg/ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
A bright, orange-red solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

For the treatment of fascioliasis (infestations of mature and immature *Fasciola hepatica*) in cattle and sheep. It is also effective, at the recommended dose rate, against adult and larval infestations of *Haemonchus contortus* in cattle and sheep, *Haemonchus placei*, *Oesophagostomum radiatum* and *Bunostomum phlebotomum* in cattle. However, Deldrax should not be regarded or used as broad spectrum anthelmintic.

4.3 Contraindications

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

Do not exceed the stated dose.

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

Ensure the injection does not enter subcutaneous muscle.

Ewes in advanced pregnancy and not intended to produce milk for human consumption should be driven, handled and dosed carefully.

Estimate the weight of sheep carefully and use injection equipment calibrated to accurately deliver the calculated dosage.

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

Wash splashes from the skin and eyes immediately. Suitable gloves should be worn to avoid staining the skin.

Deldrax solution stains and care should be taken to avoid spilling it, especially on the fleece of sheep.

4.6 Adverse reactions (frequency and seriousness)

No systemic ill-effects are to be expected when animals (including pregnant cows and ewes) are treated at normal dosage.

Small swellings are occasionally observed at the injection site in cattle, these can be avoided by injecting the dose in two separate sites and massaging well to disperse the solution.

4.7 Use during pregnancy, lactation or lay

The product 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

No signs of incompatibility are to be expected if the product is administered to cattle or sheep concurrently with therapeutic doses of the following anthelmintics: levamisole and thiabendazole, or with clostridial vaccine.

4.9 Amounts to be administered and administration route

Administration is by subcutaneous injection.
The standard dose is 10 mg nitroxynil per kg bodyweight.
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.

Taking normal aseptic precautions, the solution is injected subcutaneously at a convenient site. In sheep, this site should preferably be free from wool. The injection is then massaged gently to disperse the solution.

Sheep: In outbreaks of fascioliasis, each sheep in the flock should be treated immediately the presence of the disease is recognised, repeating treatment as necessary throughout the period when infestation is occurring, at intervals of not less than one month. On farms with fluke infested pastures, routine preventative dosing should be carried out at intervals of not less than one month, having regard for such factors as the past disease history of the farm, the frequency and severity of neighbouring outbreaks and regional forecasts of incidence.

Administer Deldrax solution according to the following dose scale:

SHEEP LIVEWEIGHT	**Deldrax Dose**
Metric	**ml**
14 - 20 kg	0.50 ml
21 - 30 kg	0.75 ml
31 - 40 kg	1.00 ml
41 - 55 kg	1.50 ml
56 - 75 kg	2.00 ml
Over 75 kg	2.50 ml

Cattle: 1.5 ml of Deldrax solution per 50 kg (1 cwt) liveweight.

Both infected and in-contact animals should be treated, treatment being repeated as considered necessary, though not more frequently than one per month. The treatment of cattle helps to reduce contamination of pasture on farms where fascioliasis is endemic or certain roundworm occurrence is evident.

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

In the event of accidental overdosage, the symptoms are pyrexia, rapid respiration and increased excitability. Patients should be kept cool, and dextrose saline should be administered intravenously.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.
Animals may be slaughtered for human consumption from 60 days after the last treatment.
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

Phamacotherapeutic group: Anthelmintics, nitroxinil.
ATCvet code: QP52AG08

5.1 Pharmacodynamic properties

The main pharmacological action of nitroxynil is fasciolicidal. The lethal action against Fasciola hepatica has been demonstrated in vitro and in vivo in laboratory animals, and in sheep and cattle. The mechanism of action is thought to be due to uncoupling of oxidative phosphorylation.

Few other pharmacodynamic effects have been observed at therapeutic doses. Hyperpnoea and increased rectal temperature are seen at high doses, and near toxic doses cause an increase in blood pressure.

5.2 Pharmacokinetic properties

The pharmacokinetics of nitroxynil in sheep and cattle are very similar. After subcutaneous injection of a single dose of 10mg/kg peak plasma levels of 83.6ug/ml are achieved at 9.3 hours in sheep, and peak plasma levels of 91.6ug/ml are achieved at 13 hours in cattle. The plasma half lives are 5 days and 8 days in sheep and cattle respectively. This slow rate of elimination is in accordance with the observed long duration of action of Deldrax against fluke in sheep and cattle.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Eglumine
Water for Injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shel-life of the vterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25^{o}C. Protect from light.

6.5 Nature and composition of immediate packaging

250 ml container of natural polypropylene with chlorobutyl rubber stopper.

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 products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/036/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

28th April 2010