**IRISH MEDICINES BOARD ACT 1995**

**MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998**

**(S.I. No.142 of 1998)**

**10989/047/001**
Case No: 7002253

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**Eurovet Animal Health B.V.**

**Handelsweg 25**, **5531 AE Bladel**, **Netherlands**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Equi-P Horse Wormer**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

# Part II

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Equi P Horse Wormer

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 26.2 g injector contains:

| Active substance | |
|---|---|
| Pyrantel (as Pyrantel Pamoate USP) | 3.63 g |

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral paste.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Horses.

### 4.2 Indications for use, specifying the target species

Equi P Horse Wormer is indicated for the treatment of a number of intestinal worm infections in horses and ponies including:

| | |
|---|---|
| Large strongyles: | *Strongylus vulgaris, S. edentatus, S. equinus.* |
| Small strongyles: | *Trichonema* spp., *Triodontophorus* spp. |
| Pinworms: | *Oxyuris equi* |
| Large roundworms: | *Parascaris equorum* |

In general only adult forms and/or lumen dwelling immature forms are sensitive to Equi P Horse Wormer.

### 4.3 Contraindications

Do not administer in combination with levamisole and piperazine. Equi P Horse Wormer should not be used in severely debilitated animals or in foals of four weeks and under.

### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

**Special precautions for use in animals**

Do not use the same injector in more than two healthy horses. In case of a diminished efficacy, consult a veterinarian.

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

Wear gloves when administering the product. If contact with the skin: wash off the paste with soap and water. Persons with a known hypersensitivity to pyrantel should not handle the preparation.

## 4.6 Adverse reactions (frequency and seriousness)

At the usual dose, there will be no side-effects.

## 4.7 Use during pregnancy, lactation or lay

Equi P Horse Wormer may be used in pregnant and lactating animals.

## 4.8 Interaction with other medicinal products and other forms of interaction

Administration of pyrantel together with cholinergic drugs may lead to potentiation of toxicity. Simultaneous administration of pyrantel with tetra- or levamisole, piperazine, methydrine or organophosphorus compounds is contraindicated.

## 4.9 Amounts to be administered and administration route

For oral administration. The general dose is 19 mg/kg pyrantel pamoate per kg body weight (e.g. horse of 550 kg body weight = 1 injector). Horses constantly reinfect themselves through grazing. Therefore periodic worming every 6 weeks may be necessary. Foals up to 8 months of age should be treated more frequently (every 4-6 weeks). Horses should be treated during the grazing season. The preparation is indicated for oral administration as a paste. Position the dosage ring at the appropriate mark using the recommended dosage (1 dose unit per 22 kg body weight). Open the mouth of the horse, and eject the contents of the injector on the back of the tongue. Raising the horse's head may assist in the swallowing process.

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

No adverse effects have been seen in horses given 20 times the recommended dose.
Even when highly overdosed this will generally not result in toxic reactions. At 20 times the recommended dose in horses, ponies and foals, pyrantel shows no adverse clinical effects or changes in blood cell values, serum choline esterase or serum glutamic oxalacetic transaminase. Symptoms of toxicity that could theoretically be seen include increased respiratory rates, ataxia and other cholinergic reactions.

## 4.11 Withdrawal Period(s)

Meat: Animals intended for human consumption may only be slaughtered from 28 days after the last treatment.
Milk: not applicable

# 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pyrantel is an imidazothiazole derivate (ATC vet code: QP52AF02). Pyrantel has been used as an anthelmintic in the form of pyrantel pamoate, -tartrate, -citrate or -HCl in horses, swine, cattle, sheep, goats, dogs and cats.
Pyrantel pamoate is a depolarizing neuromuscular blocking agent in nematodal parasites and the vertebrate host. The drug probably produces paralysis of worms by causing a contracture-inducing action of Acetylcholine (ACh). Sensitive worms will be excreted in 24-60 hours.

## 5.2 Pharmacokinetic properties

The pamoate salt of pyrantel is poorly soluble in water which offers the advantage of reduced absorption from the gut, allowing the drug to reach pinworms and be effective against them in the lower ends of the large intestine. Most of the administered pamoate is excreted unchanged in the faeces, and only a small amount is found in the urine.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Polysorbate 80
Colloidal Anhydrous Silica
Corn oil to

## 6.2 Incompatibilities

Equi P Horse Wormer is not intended for mixing with other compounds.

## 6.3 Shelf-life

The shelf life expiry date for this product shall not exceed two years from the date of its manufacture. Any content of product remaining later than 28 days after the date of first broaching of seal should be discarded.

## 6.4 Special precautions for storage

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

## 6.5 Nature and composition of immediate packaging

White high density polyethylene syringe containing an oily yellow suspension with an extrudable weight of 26.2 g

## 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

Eurovet Animal Health B.V.,
Handelsweg 25,
PO Box 179,
5530 AD Bladel,
The Netherlands.

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10989/47/1

## 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004