IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10960/048/001**
Case No: 7004011

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:

Cross Vetpharm Group Ltd.

Broomhill Road, **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:

Bimectin Horse Oral Paste 18.7 mg/g

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 previously revoked, shall continue in force from **21/11/2008**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Bimectin Horse Oral Paste 18.7mg/g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Ivermectin 18.7 mg/g

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Oral paste. A yellow, gel-like paste of uniform consistency.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of nematode or arthropod infestations in horses due to:

Large strongyles
Strongylus vulgaris (adults and 4th larval [arterial] stages)
S. edentatus (adults and 4th larval [tissue] stages)
S. equinus (adults)

Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus

Small Strongyles
Adults and immatures (fourth stage larvae) small strongyles or cyathostomes unless otherwise stated. Ivermectin is not effective against the encysted larval stages of the small strongyles.
Coronocyclus spp.
Coronocyclus coronatus
Coronocyclus labiatus
Coronocyclus labratus

Cyathostomum spp.
Cyathostomum catinatum
Cyathostomum pateratum

Cylicocyclus spp.
Cylicocyclus ashworthi
Cylicocyclus elongatus
Cylicocyclus insigne
Cylicocyclus leptostomum
Cylicocyclus nassatus

Cylicostephanus spp.
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus

Cylicodontophorus spp.
Cylicodontophorus bicornatus

Parapoteriostomum spp.
Parapoteriostomum mettami

Petrovinema spp.
Petrovinema poculatum

Poteriostomum spp.

Lungworms (adult and inhibited fourth stage larvae)
Dictyocaulus arnfieldi

Pinworms (adult and inhibited fourth stage larvae)
Oxyuris equi

Ascarids (adults and third & fourth stage larvae)

Parascaris equorum

Hairworms (adults)
Trichostrongylus axei

Large-mouth stomach worms (adults)
Habronema muscae

Neck threadworms (microfilariae)
Onchocerca spp.

Intestinal threadworms (adults)
Strongyloides westeri

Stomach bots (oral and gastric stages)
Gasterophilus spp.

4.3 Contraindications

None.

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 or misadministration of the product.

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(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.

Resistance to ivermectin has been reported in *Parascaris equorum* in horses in a number of countries, including the EU. Therefore, the use of this product should be based on local farm epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

(i) Precautions for use in animals

Special warning for non-target species: The product has been formulated for use in horses only. Cats, Dogs, especially Collies, Old English Sheepdogs and related breed or crosses, and also turtles and tortoises may be adversely affected by the concentration of ivermectin in this product if they are allowed to ingest spilled paste or have access to used syringes.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

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

Do not eat, drink or smoke while handling the product. Avoid contact with skin and eyes. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and, if necessary, get medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Some horses carrying heavy infection of *Onchocerca* microfilariae have experienced oedema and pruritus following dosing, assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.

4.7 Use during pregnancy, lactation or lay

Studies performed in laboratory animals showed no teratogenic or embryotoxic effect of ivermectin at the recommended doses during therapy.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to risk/benefit analysis by the responsible veterinary surgeon.
Please refer also to 4.11

4.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by ivermectin.

4.9 Amounts to be administered and administration route

Administer orally as a single dose rate to horses at the recommended dose level of 0.2mg ivermectin per kilogram of bodyweight. Each syringe delivers 120mg ivermectin, sufficient to treat 600kg of bodyweight.
To ensure administration of the correct dose,body weight should be determined as accurately as possible.
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 over-dosing.
This is a single dose product. Discard after use.
Dosing Instructions:
Each weight marking on the syringe plunger will deliver sufficient paste to treat 100kg bodyweight. Unlock the knurled ring by making ¼ turn and slide the knurled ring up the plunger shaft so that the side nearest the barrel is at the prescribed weight marking. Turn the knurled ring ¼ turn to lock in place. Make sure the horse's mouth contains no feed. Remove the plastic cap from the tip of the nozzle. Insert the syringe into the horse's mouth at the interdental space. Advance the plunger as far as it will go, depositing the medication on the base of the tongue. Immediately raise the horse's head for a few seconds after dosing.
The treatment schedule should be based on the local epidemiological situation.

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

Mild transitory signs (slowed pupillary light response and depression) have been seen at a dose of 1.8mg/kg (9 times the recommended dose level). Other signs seen at higher doses includes mydriasis, ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. No antidote has been identified; however, symptomatic therapy may be beneficial.

4.11 Withdrawal Period(s)

Meat and offal 34 days.
Do not use in mares producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Endectocide
ATC vet code: QP54AA01
Ivermectin is a member of the macrocyclic lactone class of endectocides.Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions and hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of theparasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).
The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic properties

Following administration of the product, ivermectin is rapidly absorbed to reach peak plasma concentration in several hours. This peak falls off gradually over several days.
Ivermectin is eliminated primarily via the faeces. The highest residue levels are found in fat.

At a dose rate of 0.2mg ivermectin per kilogram of bodyweight, plasma levels of ivermectin reach a mean C_{max} concentration of 40.44ng/ml and a mean T_{max} at 8.35 hours. This peak falls off gradually to an average level of 3 ng/ml at 10 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize oil
Polysorbate 80
Apple flavour
Colloidal anhydrous silica

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
To be used immediately after first opening the oral syringe.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

High density polyethylene pre-filled dose-graduated disposable syringe containing 6.42 g of product.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used containers.
Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Bimeda
(A division of Cross Vetpharm Group Ltd.)
Broomhill Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/048/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st November 2008

10 DATE OF REVISION OF THE TEXT