

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10960/027/001**

Case No: 7004208

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:

Endospec 10% SC

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 **13/03/2008**.

Signed on behalf of the Irish Medicines Board

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

Endospec 10% SC

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Substance:</u>	per ml
Albendazole	100 mg

<u>Excipients:</u>	
Selenium (as Sodium Selenite)	1.08 mg
Cobalt (as Cobalt Sulphate)	2.5 mg
Green S (E142)	0.018 mg (as colour)
Methyl Parahydroxybenzoate (E218)	2 mg (as preservative)
Propyl Parahydroxybenzoate (E216)	0.2 mg (as preservative)

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep.

4.2 Indications for use, specifying the target species

Endospec 10% SC is a broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult liver fluke in cattle and sheep. The product is also ovicidal against fluke and roundworm eggs.

In **sheep** it is active against benzimidazole-susceptible strains of the following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus* (including *N. battus*), *Chabertia* and *Oesophagostomum*.

It is usually effective against inhibited larvae of *Ostertagia*.

Lungworms: *Dictyocaulus filaria*.

Tapeworms: *Moniezia* spp.

Adult liver fluke: *Fasciola hepatica*

In **cattle** it is active against the following species:

Roundworms: *Ostertagia*, *Haemonchus*, *Trichostrongylus*, *Nematodirus*, *Oesophagostomum*, *Bunostomum*, *Cooperia* and *Strongyloides* spp. It is usually effective against inhibited larvae of *Cooperia* and *Ostertagia*.

Lungworms: *Dictyocaulus viviparus*.

Tapeworms: *Moniezia* spp.

Adult liver fluke: *Fasciola hepatica*.

Endospec 10% SC is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

4.3 Contraindications

Do not use in sheep producing milk for human consumption.

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

Do not administer other cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary practitioner.

4.4 Special warnings for each target species

Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment.

4.5 Special precautions for use

Special precautions for use in animals

Not to be diluted or mixed with other products.

Avoid the introduction of contamination during use.

The product should only be used in areas where deficiencies of cobalt and selenium are likely to occur. If in any doubt seek the advice of your Veterinary Practitioner.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your Veterinary Practitioner.

Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep.

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

Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not dose ewes at the 'fluke and worm' dose rate, (7.5 mg/kg), during tupping or for 1 month after removing the rams.

The use of Endospec 10% SC in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

4.8 Interaction with other medicinal products and other forms of interaction

Administration of ionophores to lambs has been shown to enhance selenium bioavailability. Concurrent administration of ionophores and Endospec 10% SC may therefore lead to an increased risk of selenium toxicity.

4.9 Amounts to be administered and administration route

For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately. One ml of Endospec 10% SC contains 100 mg Albendazole, 1.08 mg elemental selenium and 2.5 mg elemental cobalt.

Shake the container before use.

Cattle:

Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs.

Dosage: Approximately 7.5 mg albendazole per kg bodyweight.

Fluke and worm dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle.

Dosage: Approximately 10 mg albendazole per kg bodyweight.

Sheep:

Worm dose: For the control of roundworms, lungworms, tapeworms, fluke and roundworm eggs.

Dosage: Approximately 5 mg albendazole per kg bodyweight.

Fluke and Worm Dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep.

Dosage: Approximately 7.5 mg albendazole per kg bodyweight.

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

Not applicable.

4.11 Withdrawal Period(s)

Cattle

Meat: 14 days. Animals intended for human consumption may be slaughtered after 14 days following treatment.

Milk: 60 hours. Milk intended for human consumption may be taken from animals after 60 hours following treatment.

Sheep

Meat: 4 days. Animals intended for human consumption may be slaughtered after 4 days following treatment.

Milk: Not for use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Albendazole belongs to the benzimidazole class of anthelmintics.

Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in the absence of microtubules in the intestinal cells of the nematode, with the result that these cells cannot absorb nutrients, thus causing a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, resulting in the preferential toxicity of albendazole to the helminth and not to the host. Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production.

The selenium and cobalt are trace elements of use as nutritional supplements and are not intended to be used therapeutically.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Selenium (as Sodium Selenite)
Cobalt (as Cobalt Sulphate)
Green S (E142)
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Citric Acid Monohydrate
Sodium Citrate
Xanthan Gum
Povidone K90
Polysorbate 20
Propylene Glycol
Simethicone emulsion
Purified Water

6.2 Incompatibilities

Not to be diluted or mixed with other products.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

1 litre, 2.5 litre and 5 litre high density polyethylene containers and high density polyethylene closures with expanded polyethylene liners.

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

Any 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

Cross Vetpharm Group Ltd
Broomhill Road
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/27/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd September 1996/23rd September 2001

10 DATE OF REVISION OF THE TEXT

13th March 2008