

PART III

SUMMARY OF PRODUCT CHARACTERISTICS

1. **Name of the Veterinary Medicinal Product**

Endospec 2.5% SC

2. **Qualitative and Quantitative Composition**

Active Substances per ml

Albendazole	25 mg
Selenium (as sodium selenite)	0.27 mg
Cobalt (as cobalt sulphate)	0.624 mg

Excipients

Chlorophyll WSI (E141)	3 mg (colour)
Methyl Parahydroxybenzoate (E218)	2 mg (preservative)
Propyl Parahydroxybenzoate (E216)	0.2 mg (preservative)

3. **Pharmaceutical Form**

Oral suspension

4. **Pharmacological 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.

5. CLINICAL PARTICULARS

5.0 Target Species

Cattle, sheep.

5.1 Indications for Use, Specifying the Target Species

Endospec 2.5% 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 2.5% SC is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

The selenium and cobalt in this product are trace elements of use as nutritional supplements.

5.2 Contra-indications

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 Surgeon.

5.3 Undesirable Effects (Frequency and Seriousness)

None known.

5.4 Special precautions for use

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 Surgeon.

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

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

5.5 Use During Pregnancy and Lactation

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 2.5% SC in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

5.6 Interaction with other Medicaments and other Forms of Interaction

Administration of ionophores to lambs has been shown to enhance selenium bioavailability. Concurrent administration of ionophores and Endospec 2.5% SC may therefore lead to an increased risk of selenium toxicity.

5.7 **Posology and Method of Administration**

For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately. One ml of Endospec 2.5% SC contains 25 mg Albendazole, 0.27 mg elemental selenium and 0.624 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.

5.8 **Overdose (Symptoms, Emergency Procedures, Antidotes) (if Necessary)**

Not applicable.

5.9 **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.

5.10 Withdrawal Periods

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.

5.11 Special Precautions to be taken by the Person Administering the 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.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

Not to be diluted or mixed with other products.

6.2 Shelf-life

3 years.

6.3 Special Precautions for Storage

Do not store above 25 °C.

6.4 Nature and Contents of Container

2.5 litre, 5 litre and 10 litre high density polyethylene containers and high density polyethylene closures with expanded polyethylene liners, containing a pale green suspension.

6.5 Name and Address of Veterinary Product Authorisation Holder

Cross Vetpharm Group Ltd
Broomhill Road
Tallaght,
Dublin 24.

6.6 Special Precautions for the Disposal of Unused Product or Waste Materials, if any

Do not contaminate ponds, waterways or ditches with the product or used containers. Unused product and waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7. FINAL INFORMATION

7.1 Marketing Authorisation Number

VPA 10960/28/1

7.2.1 Date of Approval/

23rd September 2001

7.2.2 Revision of SPC