

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endospec SC 2.5% w/v Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Constituents</u>	<u>%w/v</u>
Albendazole	2.5
<u>Excipients</u>	
Methyl Parahydroxybenzoate	0.2
Propyl Parahydroxybenzoate	0.02
Copper Chlorophyll Complex Sodium (E141)	0.3
<u>Other Relevant Constituents</u>	
Cobalt Sulphate Heptahydrate	0.3
(Equivalent to Cobalt)	0.0624
Sodium Selenite	0.0592
(Equivalent to Selenium)	0.027

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep

4.2 Indications for use, specifying the target species

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 **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*.

The product is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

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*.

The product is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

4.3 Contraindications

Known hypersensitivity to the active ingredient

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.

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, misadministration of the product, or lack of calibration of the dosing device (if any).

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 test(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 benzimidazoles (which includes albendazole) has been reported in *Cooperia*, *Haemonchus*, *Trichostrongylus*, and *Teladorsagia* species in small ruminants in a number of countries, including the EU. Resistance to albendazole has been reported in *Cooperia* and *Teladorsagia* species in cattle in developed countries such as New Zealand. Therefore the use of this product should be based on local (regional, 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) 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 a veterinary surgeon.

Do not administer other cobalt and selenium supplements concurrently unless specifically advised by your veterinary surgeon.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with a veterinary surgeon.

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

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

Avoid direct contact with the product. Wear suitable protective clothing including impermeable rubber gloves. In the event of accidental eye exposure, flush eye thoroughly with running water. If irritation persists, seek medical attention. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The use of the product in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

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. Can be safely used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only using properly calibrated dosing equipment. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Shake the container before use.

Cattle:

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

Dosage: 7.5 mg albendazole per kg bodyweight.

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

Dosage: 10 mg albendazole per kg bodyweight.

Sheep:

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

Dosage: 5 mg albendazole per kg bodyweight.

Fluke and Worm Dose

For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep.

Dosage: 7.5 mg albendazole per kg bodyweight.

Administration with a suitable drenching gun is recommended

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

Not applicable.

4.11 Withdrawal period(s)

Animals intended for human consumption must not be slaughtered during treatment. Cattle must not be slaughtered for human consumption until 14 days after the last treatment. Sheep must not be slaughtered for human consumption until 4 days after the last treatment.

Milk intended for human consumption may be taken from cows only after 60 hours from the last treatment. Not for use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic (Class 1-BZ)

ATCvet code: QP52AC11

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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

Environmental properties

DANGEROUS to aquatic life. Do not contaminate ponds, waterways or ditches with the product or used containers. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Copper Chlorophyll Complex Sodium (E141)
Cobalt Sulphate Heptahydrate
Sodium selenite
Citric Acid Monohydrate
Sodium Citrate
Xanthan Gum
Povidone
Polysorbate 20
Propylene Glycol
Simethicone Emulsion
Water purified

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the 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

10 Litres white high density polythene jerricans and white high density polythene closures with induction heat seal.

1.0, 2.5 and 5.0 Litres and 15L (3x5 Litres) high density polyethylene backpacks with high density polyethylene caps (screw-fit).

The 15 L (3x5 Litres) pack has a 1x10 ml drencher for sheep included).
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

DANGEROUS to aquatic life. Do not contaminate ponds, waterways or ditches with the product or used containers. 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

Bimeda Animal Health Limited
2 / 3 / 4 Airtown Close
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4030

9. DATE OF FIRST AUTHORISATION

02 April 1996

10. DATE OF REVISION OF THE TEXT

October 2018

Approved: 25 October 2018

D. Austin