[Version 9, 03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endospec 100 mg/ml SC Oral Suspension for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Albendazole 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Selenium (as Sodium Selenite)	1.08 mg
Cobalt (as Cobalt Sulphate)	2.5 mg
Green S (E142)	0.018 mg
Methyl Parahydroxybenzoate (E218)	2 mg
Propyl Parahydroxybenzoate (E216)	0.2 mg
Citric Acid Monohydrate	
Sodium Citrate	
Xanthan Gum	
Povidone K90	
Polysorbate 20	
Propylene Glycol	
Simethicone emulsion	
Purified Water	

A pale blue suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle
Sheep

3.2 Indications for use for each target species

This veterinary medicinal product 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 veterinary medicinal 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.*

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

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer other cobalt and selenium supplements concurrently with this veterinary medicinal product unless specifically advised by your Veterinary Practitioner.

3.4 Special warnings

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd/flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd/flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd/flock should be sought from the responsible veterinarian.

The use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g., Faecal Egg Count Reduction test (FECRT)).

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

3.5 Special precautions for use

<u>Special precautions for safe use in the target species:</u>
Not to be diluted or mixed with other products.

Avoid the introduction of contamination during use.

The veterinary medicinal 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 veterinary medicinal product to animals:
Direct contact with the skin should be kept to a minimum.

Personal protective equipment consisting of protective clothing including impermeable rubber gloves should be worn when handling the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the Contact details section of the package leaflet for respective contact details.

3.7 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.

Use of the veterinary medicinal product in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

3.8 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 this veterinary medicinal product may therefore lead to an increased risk of selenium toxicity.

3.9 Administration routes and dosage

For oral administration only using properly calibrated dosing equipment. 1 ml of the veterinary medicinal product contains 100 mg Albendazole, 1.08 mg elemental selenium and 2.5 mg elemental cobalt.

Shake the container before use.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogenous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Accuracy of the dosing device should be thoroughly checked.

DOSAGE TABLES:

Cattle		
Bodyweight	**Worm Dose (7.5 mg/kg)**	**Fluke & Worm Dose (10.0 mg/kg)**
60 kg	4.5 ml	6.0 ml
100 kg	7.5 ml	10.0 ml
200 kg	15.0 ml	20.0 ml
300 kg	22.5 ml	30.0 ml
400 kg	30.0 ml	40.0 ml
Cattle over 400 kg – give a further 3.75 ml (Worm Dose) or 5 ml (Fluke and Worm Dose) for each additional 50 kg body weight.		

Sheep		
Bodyweight	**Worm Dose (5.0 mg/kg)**	**Fluke & Worm Dose (7.5 mg/kg)**
10 kg	0.5 ml	0.75 ml
11 – 20 kg	1.0 ml	1.50 ml
21 – 30 kg	1.5 ml	2.25 ml
31 – 40 kg	2.0 ml	3.00 ml
41 – 50 kg	2.5 ml	3.75 ml
51 – 60 kg	3.0 ml	4.50 ml
61 – 70 kg	3.5 ml	5.25 ml
71 – 80 kg	4.0 ml	6.00 ml
Sheep over 80 kg – give a further 0.5 ml (Worm Dose) or 0.75 ml (Fluke and Worm Dose) for each additional 10 kg body weight.		

Cattle:
Worm Dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs.
Dosage: Approximately 7.5 mg albendazole per kg body weight, which equates to approximately 4.5 ml of product per 60 kg body weight.

Fluke and Worm Dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle.
Dosage: Approximately 10 mg albendazole per kg body weight, which equates to approximately 6 ml of product per 60 kg body weight.

Sheep:
Worm Dose: For the control of roundworms, lungworms, tapeworms, fluke and roundworm eggs.
Dosage: Approximately 5 mg albendazole per kg body weight, which equates to approximately 0.5 ml of product per 10 kg body weight.

Fluke and Worm Dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep.
Dosage: Approximately 7.5 mg albendazole per kg body weight, which equates to approximately 0.75 ml of product per 10 kg body weight.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 14 days.
Milk: 60 hours.

Sheep:
Meat and offal: 4 days.
Milk: Not authorised for use in sheep producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC11

4.2 Pharmacodynamics

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. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 ˚C.

5.4 Nature and composition of immediate packaging

1 litre, 2.5 litre, 5 litre, 6 litre (5L & 1L) and 7.5 litre (5L & 2.5L) high density polyethylene containers and high density polyethylene closures with expanded polyethylene liners.

Not all pack sizes may be marketed.

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

Do not contaminate ponds, waterways or ditches with the product or used containers.

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited.

7. MARKETING AUTHORISATION NUMBER

VPA 22033/016/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 23 September 1996

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).