

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Pack Label 1 L, 2.5 L, 5 L, 10 L

[There is no carton for the 2.5 L, 5 L and 10 L packs.

Package leaflet information will be printed on the immediate packaging]

1. Name and address of the marketing authorisation holder and of the manufacturer responsible for batch release, if different

MAH:

Bimeda Animal Health Limited

2, 3, 4 Airton Close

Tallaght

Dublin 24

IE-D24 E032

Ireland

Chanelle Pharmaceuticals Manufacturing Limited,

Loughrea,

Co. Galway

Ireland

Please note: Chanelle Pharmaceuticals Manufacturing Limited will be removed as a manufacturer and batch release site by a 1A variation submission by Bimeda Animal Health Limited by August 2020

Distributor:

Bimeda®, Cross Vetpharm Group UK Ltd.,

Unit 2, Bryn Cefni, Llangefni, Anglesey, LL77 7XA, UK

2. Name of the veterinary medicinal product

Endospec SC 10% w/v Oral Suspension for Cattle and Sheep.

Albendazole

3. Statement of the active substance (s) and other ingredients

Active substances:

%w/v

Albendazole

10.0

List of excipients:

Sodium Selenite (Equivalent to Selenium)

0.237 (0.108)

Cobalt Sulphate Heptahydrate (Equivalent to Cobalt)

1.2 (0.25)

Brilliant Green BS (E142)

0.0015 (colour)

Methyl Parahydroxybenzoate (E218)

0.2 (preservative)

Propyl Parahydroxybenzoate (E216)

0.02 (preservative)

4. Pharmaceutical form

Oral Suspension.

5. Package size

1 L
2.5 L
5 L
10 L

6. Indication(s)

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

7. Contraindications

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.

8. Adverse reactions

None known.

If you notice any side-effects or you think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Cattle and sheep.

10. Dosage for each species, route(s) and method of administration

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 dosing device should be checked.

Shake the container before use.

DOSAGE TABLE:

CATTLE			SHEEP		
Bodyweight	Worm Dose (7.5 mg/kg)	Fluke & Worm (10 mg/kg)	Bodyweight	Worm Dose (5.0 mg/kg)	Fluke & Worm (7.5 mg/kg)
60 kg	4.50 ml	6.0 ml	Up to 10 kg	0.5 ml	0.75 ml
100 kg	7.50 ml	10.0 ml	11 – 20 kg	1.0 ml	1.50 ml
200 kg	15.00 ml	20.0 ml	21 – 30 kg	1.5 ml	2.25 ml
300 kg	22.50 ml	30.0 ml	31 – 40 kg	2.0 ml	3.00 ml
400 kg	30.00 ml	40.0 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

Cattle over 400 kg – give a further 3.75 ml (worm dose) or 5 ml (fluke and worm dose) for each additional 50 kg bodyweight.

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 bodyweight.

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.

11. Advice on correct administration

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

12. Withdrawal period(s)

Withdrawal period(s):

Cattle

Meat and offal: 14 days

Milk: 60 hours

Sheep

Meat and offal: 4 days

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

13. Special storage precautions

Do not store above 25°C

14. Special warning(s)

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.

Special precautions for use in animals:

Not to be diluted or mixed with other products.

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

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.

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.

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.

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.

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 the product may therefore lead to an increased risk of selenium toxicity.

Overdose (symptoms, emergency procedures, antidotes):

Not applicable.

Incompatibilities:

Not to be diluted or mixed with other products.

15. Special precautions for the disposal of unused product or waste materials, if any
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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.

16. Date on which the label was last approved
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September 2020

17. Other information

Available in 1 L, 2.5 L, 5 L and 10 L pack size.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Ireland

Bimeda Animal Health Limited
2, 3, 4 Airtown Close
Tallaght
Dublin 24
IE-D24 E032
Ireland
Tel: + 353 (0) 1 4667900

1-BZ

18. The words “For animal treatment only” and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

POM-VPS

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

<EXP {month/year}>

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

21. Marketing authorisation number(s)

Vm 50146/4025

22. Manufacturer’s batch number

<Batch> <Lot>

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton 1 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Endospec SC 10% w/v Oral Suspension for Cattle and Sheep
Albendazole

2. STATEMENT OF ACTIVE SUBSTANCES

<u>Active substances:</u>	%w/v
Albendazole	10.0
<u>List of excipients:</u>	
Sodium Selenite (Equivalent to Selenium)	0.237 (0.108)
Cobalt Sulphate Heptahydrate (Equivalent to Cobalt)	1.2 (0.25)
Brilliant Green BS (E142)	0.0015 (colour)
Methyl Parahydroxybenzoate (E218)	0.2 (preservative)
Propyl Parahydroxybenzoate (E216)	0.02 (preservative)

3. PHARMACEUTICAL FORM

Oral Suspension.

4. PACKAGE SIZE

1 L

5. TARGET SPECIES

Cattle and sheep.

6. INDICATION(S)

Endospec SC 10% 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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 dosing device should be checked.
Shake the container before use.

CATTLE		
Bodyweight	Worm Dose (7.5 mg/kg)	Fluke & Worm Dose (10 mg/kg)
60 kg	4.50 ml	6.0 ml
100 kg	7.50 ml	10.0 ml
200 kg	15.00 ml	20.0 ml
300 kg	22.50 ml	30.0 ml
400 kg	30.00 ml	40.0 ml

Cattle over 400kg – give a further 3.75 ml (worm dose) or 5 ml (fluke and worm dose) for each additional 50 kg bodyweight.

SHEEP		
Bodyweight	Worm Dose (5.0 mg/kg)	Fluke & Worm Dose (7.5 mg/kg)
Up to 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 bodyweight.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Cattle

Meat and offal: 14 days

Milk: 60 hours

Sheep

Meat and offal: 4 days

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the label before use.

Not to be diluted or mixed with other products.

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

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.

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.

10. EXPIRY DATE

<EXP {month/year}>

Shelf life of the veterinary medicinal product as packaged for sale: 18 years

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See label.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

POM-VPS

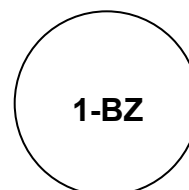
Available in 1 L, 2.5 L, 5 L and 10 L pack size.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Ireland

Bimeda Animal Health Limited
2, 3, 4 Airton Close
Tallaght
Dublin 24
IE-D24 E032
Ireland
Tel: + 353 (0) 1 4667900



14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MAH:
Bimeda Animal Health Limited
2, 3, 4 Airton Close
Tallaght
Dublin 24
IE-D24 E032
Ireland

Distributor:
Bimeda®, Cross Vetpharm Group UK Ltd.,
Unit 2, Bryn Cefni, Llangefni, Anglesey LL77 7XA, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/4025

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot>

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved 17 September 2020