SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Benzimole 25 mg/ml SC Oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active Substance	
Albendazole	25 mg
Excipients	
Copper chlorophyll complex sodium (E141)	2.3 mg
Methyl parahydroxybenzoate	2.0 mg
Propyl parahydroxybenzoate	0.2 mg
Other Relevant Constituents	
Sodium Selenite (equiv. to 0.27 mg Se)	0.59 mg
Cobalt Sulphate (equiv. to 0.63 mg Co)	2.98 mg

For the full list of excipients, see 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension
Pale green, free flowing suspension

4. CLINICAL PARTICULARS

4.1. Target Species

Cattle, 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: *Teladorsagia (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*.

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.

The product also contains selenium and cobalt as nutritional supplements.

4.3. Contra-indications

Known hypersensitivity to the active ingredient.

4.4. Special warnings for each target species

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 bodyweight.

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 *Teladorsagia, Haemonchus, Cooperia* and *Trichostrongylus* 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.

Selenium and cobalt are included as nutritional supplements and are not intended to be used therapeutically. Administration of ionophores to lambs has been shown to enhance selenium bioavailability. Concurrent administration of ionophores and Benzimole 25 mg/ml SC may therefore lead to an increased risk of selenium toxicity.

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

i) Special precautions for use in animals

Do not administer other cobalt and selenium supplements concurrently unless advised by you veterinary surgeon. Not to be diluted

ii) Special precautions for the person administering the veterinary medicinal product to animals

Direct contact with the skin should be kept to a minimum. 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. In the event of accidental skin exposure, wash the affected area with soap and 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

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. The use of the product 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

None known.

4.9. Amounts to be administered and administration route

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked
For oral administration.
Do not mix with other products.
One ml of Benzimole 25 mg/ml SC contains 25 mg Albendazole, 0.27 mg of selenium and 0.63 mg of cobalt.
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 b.w.
Fluke and worm dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle.
Dosage: 10 mg albendazole per kg b.w.

Sheep:
Worm dose: For the control of roundworms, lungworms, tapeworms, fluke and roundworm eggs.
Dosage: 5 mg albendazole per kg b.w.
Fluke and Worm Dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep.
Dosage: 7.5 mg albendazole per kg b.w.

4.10. Overdose (symptoms, emergency procedures, antidotes)

Benzimidazoles have a wide margin of safety. No treatment specified.

4.11. Withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero

Cattle (meat and offal):	14 days
Cattle (milk):	60 hours
Sheep (meat):	5 days

Not to be used in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATCVet Code: QP52AC11

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.
Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production.
The selenium and cobalt in this product are trace elements of use as nutritional supplements.

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.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Copper chlorophyll complex (E 141)
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Sodium selenite
Cobalt sulfate
Citric acid monohydrate (pH adjustment)
Sodium citrate dehydrate (pH adjustment)
Xanthan gum
Povidone 90
Polysorbate 20
Simethicone emulsion
Propylene glycol
Water, purified

6.2. Incompatibilities

None known

6.3. Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage precautions.

6.5. Nature and composition of immediate packaging

High density polythene bottles (jerricans) with high density polyethylene screw fit, tamper evident closures and expanded polyethylene liners containing 1L, 2.5l, 5L or 10L of product.

High density polyethylene flexipack containers with polypropylene screw fit closures, and aluminium foil sealed, polyfaced steran liners containing 1L, 2.5L or 5L of product
Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate.

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

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

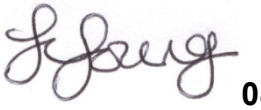
Vm: 08749/4040

9. DATE OF RENEWAL OF THE AUTHORISATION

Date: 26 February 2007

10. DATE OF THE REVISION OF THE TEXT

Date: April 2014

Approved:  **08/04/2014**