SUMMARY OF THE PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product:

ALBACERT 2.5% w/v SC Oral Suspension

2. Qualitative and Quantitative Composition:

Active substance

Albendazole	2.5% w/v

Excipients:

Methyl Parahydroxybenzoate	0.2% w/v
Propyl parahydroxybenzoate	0.02% w/v
Copper chlorophyll complex E 141	0.23% w/v

Other relevant Constituents:

Sodium selenite	0.059% w/v
(equivalent to 0.027% Se)	
Cobalt sulphate	0.298% w/v
(equivalent to 0.063% Co)	

For the full list of excipients, see section 6.1

3. Pharmaceutical Form:

Oral suspension.

A pale green, free-flowing.

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: *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:

Do not use in cases of known hypersensitivity to the active substance or to any of the other constituents.

4.4 Special Warnings

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 Albex 2.5% 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.
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 a different 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.

4.5 Special precautions for use:

(i) Special precautions for use in animals

Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep. Selenium and cobalt are included as nutritional supplements and are not intended to be used therapeutically. Do not administer other cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary surgeon.

Not to be diluted or mixed with other products.

Avoid the introduction of contamination during use.

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

The product should only be used in areas where deficiencies of selenium and cobalt are likely to occur. In cases of doubt, consult a veterinary surgeon.

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

Wash hands after use.

Avoid direct contact with the product.

Wear suitable 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 effected area with soap and water. If irritation persists, seek medical attention.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 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. 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:

For oral administration**.**

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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), if necessary:

No treatment specified.

4.11 Withdrawal periods:

Cattle:
Meat & Offal: 14 days
Milk: 60 hours

Sheep:
Meat & Offal: 5 days
Not to be used in sheep producing milk for human consumption.

5. Pharmacological Properties:

Pharmacotherapeutic group: Anthelmintics; Benzimidazoles and related substances.
ATC vet 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. 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 in this product are trace elements of use as nutritional supplements.

5.2 Pharmacokinetic particulars

Albendazole has poor water solubility and limited absorption from the gastrointestinal tract (about 50% of the oral dose is absorbed in cattle).
Following absorption, there is rapid first pass metabolism in the liver and the sulphide moiety of albendazole is oxidised to the pharmacologically active sulphoxide, then the sulphone, followed by deacetylation of the carbamate group to form the 2-aminosulphone.

6. Pharmaceutical Particulars

6.1 List of excipients:

Copper Chlorophyll Complex Sodium E141
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Sodium selenite
Cobalt sulfate
Citric Acid Monohydrate (for pH adjustment)
Sodium citrate dihydrate (for 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 conditions

6.5 Nature and composition of immediate packaging:

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

High density polyethylene flexipack containers with polypropylene screw-fit closures, and aluminium foil sealed polyfaced steran liners containing 1 L, 2.5 L or 5 L of product.

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 fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. 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:

Chanelle Animal Health Ltd.,
7 Rodney Street,
Liverpool L1 9HZ,
UK.

8. MARKETING AUTHORISATION NUMBER

Vm 11990/4050

9. DATE OF FIRST AUTHORISATION

Date: 02/04/2009

10. DATE OF REVISION OF THE TEXT

Date: December 2013

Approved:  **23/12/2013**