Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Albex 2.5 % Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Albendazole	2.5	% w/v

Excipients:

Chlorophyll WS1, E141	0.3	% w/v
Methyl parahydroxybenzoate E218	0.2	% w/v
Propyl parahydroxybenzoate E216	0.02	% w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral suspension.
A pale green, free flowing suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep

4.2 Indications for use, specifying the target species

Albex 2.5% 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 **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*
Tapeworm: *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*

Albex 2.5% is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Not for use in sheep producing milk for human consumption.
Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after infection. Intensive use or misuse of anthelmitics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon. Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep.

4.5 Special precautions for use

Special precautions for use in animals

Not to be diluted or mixed with other products.
Avoid the introduction of contamination during use.

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. Wear suitable protective clothing including impermeable rubber gloves. 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. Albex 2.5% can be safely used during lactation.

The use of Albex 2.5% 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 interactions

None known.

4.9 Amounts to be administered and administration route

For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately. One ml of Albex 2.5% contains 25 mg Albendazole. Shake the container before use.

Cattle:
Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs.
Dosage: Approximately 7.5 mg albendzole per kg bodyweight.
Fluke and worm dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle.
Dosage: Approximately 10 mg albendazole per kg bodyweight.

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

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

Not applicable.

4.11 Withdrawal period(s)

Animals intended for human consumption should not be slaughtered during treatment. Cattle must not be slaughtered for human consumption until after 14 days after last treatment. Sheep must not be slaughtered for human consumption until after 4 days after last treatment.
Milk intended for human consumption may be taken from cows only after 60 hours after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Albex 2.5% 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.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Citric Acid Monohydrate
Sodium Citrate
Chlorophyll WS 1 (E141)
Xanthan Gum
Povidone 90
Polysorbate 20
Propylene Glycol
Simethicone Emulsion
Purified Water

6.2 Major 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

1.0 L, 2.5 L, 5.0 L and 10 L white standard containers or 1 L, 2.5 L and 5 L flexi-packs.

Standard Pack
Container: HDPE
Closure: HDPE
Cap liner: Expanded polyethylene
Tamper evidence: Closure is tamper evident

Flexi pack (vaccine pack)
Container: HDPE
Closure: Homo polymer polypropylene
Cap liner: Polyfaced steran wad
Tamper evidence: Aluminium foil seal

Flexi pack (flat bottomed stand alone)
Container: HDPE
Closure: Copolymer polypropylene
Cap liner: Polyfaced steran wad
Tamper evidence: Closure is tamper evident

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

Do not contaminate ponds, waterways or ditches with the product or used containers.
Dispose of used containers safely.
Unused product should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/142/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd April 1996
Date of last renewal: 21st April 2006

10 DATE OF REVISION OF THE TEXT

November 2018