

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Albex 10 % Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Albendazole	10.00	% w/v
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Excipients:

Green S (E142)	0.0018	% 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 blue, free flowing suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep

4.2 Indications for use, specifying the target species

Albex 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 **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*.

Albex 10% 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 anthelmintics 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 tugging or for 1 month after removing the rams. Albex 10% can be safely used during lactation. The use of Albex 10% 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 using properly calibrated dosing equipment. Estimate bodyweight accurately. One ml of Albex 10% contains 100 mg Albendazole.

Cattle:

Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs.

Dosage: Approximately 7.5 mg albendazole 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 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 the last treatment.

Sheep must not be slaughtered for human consumption until after 4 days after the 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 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.

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
Green S (E142)
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 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

0.5 L, 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 or waste material 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)

VPA10987/142/002

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