SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albex 10% w/v oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Albendazole 10% w/v

Excipient(s):
Methyl Parahydroxybenzoate 0.2 % w/v
Propyl Parahydroxybenzoate 0.02 % w/v
Green S E142 0.0018 % w/v

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension.
A pale blue, free-flowing oral suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and 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.

4.3 Contraindications

Known hypersensitivity to the active ingredient.

4.4 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 infection.

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 and extended period of time.
- Underdosing, which may be due to undersestimation 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 results strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class having a different mode of action should be used.
Resistance to benzimidazoles (which includes albendazole) has been reported in *Teladorsagia Haemonchus, Cooper 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

Not to be diluted or mixed with other products.
Avoid the introduction of contamination during use.
Care must be taken not to damage the pharyngeal region during dosing, particularly in sheep.
Intensive use or misuse of anthelmintics can give rise to resistance. To reduce the risk, dosing programmes should be discussed with 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 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 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, 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.
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 only using properly calibrated dosing equipment. To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
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: 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.

Do not mix with other products.

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

No treatment specified.

4.11 Withdrawal period(s)

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: A broad spectrum multi-purpose anthelmintic, Benzimidazole.

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 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
Green S (E142)
Citric acid monohydrate
Sodium citrate
Xanthan Gum
Povidone 90
Polysorbate 20
Propylene glycol
Simethicone emulsion
Purified Water

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

No special precautions for strorage.

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 1L, 2.5 L, 5 L or 10L of product. High density polyethylene, flat-bottomed, “stand-alone”, 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.
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 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 Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/3022

9. DATE OF FIRST AUTHORISATION

1 April 1996

10. DATE OF REVISION OF THE TEXT

September 2025

Gavin Hall
Approved: 11 September 2025