1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albex 100 mg/ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Albendazole 100 mg/ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Green S (E142)	0.018 mg/ml
Methyl parahydroxybenzoate (E218)	2 mg/ml
Propyl parahydroxybenzoate (E216)	0.2 mg/ml
Citric Acid Monohydrate	---------
Sodium Citrate	---------
Xanthan Gum	---------
Povidone 90	---------
Polysorbate 20	---------
Propylene Glycol	---------
Simethicone Emulsion	---------
Purified Water	---------

A pale blue, free flowing suspension.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle and sheep.

3.2 Indications for use for each target species

The veterinary medicinal product 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*.

The veterinary medicinal product is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

3.3 Contraindications:

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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. Personal protective equipment consisting of suitable protective clothing and impermeable rubber gloves should be worn when handling the veterinary medicinal product. Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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. The product can be safely used during lactation.
The use of the product in pregnant cattle is not expected to interfere with their reproductive performance.

Fertility:
The use of the product in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
The use of suitably calibrated measuring equipment is recommended. To ensure a correct dosage, body weight should be determined as accurately as possible.

One ml of the veterinary medicinal product 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 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal Periods

Cattle:
Meat and offal: 14 days
Milk: 60 hours.

Sheep:
Meat and offal: 4 days.
Milk: Not authorised for use in sheep producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC11

4.2 Pharmacodynamics

the product 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

0.5L, 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 bottom 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Dispose of used containers safely.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/142/002

8. DATE OF FIRST AUTHORISATION

22 April 2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).