SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albex Advance 200 mg/ml oral suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:
Active substance:
Albendazole 200.0 mg

Excipients:
Methyl Parahydroxybenzoate (E218) 2.0 mg
Propyl Parahydroxybenzoate 0.2 mg
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension
White to off white suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

Indications:
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. The product is also ovicidal against fluke and roundworm eggs.

Roundworms: *Ostertagia, Chabertia, 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*.
The veterinary medicinal product is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination

4.3 Contraindications

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

4.4 Special warnings for each target species

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 bodyweight, 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 belonging to another 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

Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after infection.
Care must be taken not to damage the pharyngeal region when dosing.

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
This product may cause skin and eye irritation and dermal sensitisation.
Direct contact with the skin and eyes should be kept to a minimum.
Personal protective equipment, including impermeable rubber gloves, should be worn when handling the product.
In case of accidental spillage onto skin, wash the affected area with soap and water.
In case of accidental eye exposure, flush eye thoroughly with running water.
If skin or eye irritation persists seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands and exposed skin after use.
Do not smoke, eat or drink while handling the product.

Other precautions
Faeces containing albendazole and its main transformation products excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation. Treated animals (cattle) should not have access to surface water for 7 days after treatment to avoid adverse effects on aquatic organisms.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The use of the veterinary medicinal 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 using properly calibrated dosing equipment. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under or over dosing'.
One ml of the veterinary medicinal product contains 200 mg Albendazole.

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.

Cattle		
Bodyweight	Worm dose (7.5 mg/kg)	Fluke & worm dose (10 mg/kg)
100 kg	3.75 ml	5.0 ml
200 kg	7.5 ml	10.0 ml
300 kg	11.25 ml	15.0 ml
400 kg	15.0 ml	20.0 ml
500 kg	18.75 ml	25.0 ml
600 kg	22.5 ml	30.0 ml

Cattle over 600 kg give a further 3.75 or 5 ml for each additional 100 kg bodyweight

Shake the container before use

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

Not applicable

4.11 Withdrawal period

Cattle:
Meat and offal: 14 days.
Milk: 72 hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Albendazole
ATCvet code: QP52AC11.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

Albendazole is quickly metabolised to albendazole sulphoxide which persists at higher levels in bovine plasma for a longer duration after oral administration with peak plasma levels approximately 15 hours after dosing. After oral administration of the product to cattle at a dose rate of 10 mg albendazole sulphoxide per kg bodyweight the following parameters were observed: C_{max} of 1951.43 ng/ml, t½ of 2.4 hours and AUC of 32319.0 ng.h/ml. Excretion is predominantly faecal, biliary excretion being the most important route of elimination (cattle studies only).

5.3 Environmental properties

Albendazole is quickly metabolised to albendazole sulfoxide. Albendazole sulfoxide has been shown to be very persistent in soils.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate
Citric Acid Monohydrate

Sodium Citrate
Xanthan Gum
Povidone 90
Polysorbate 20
Propylene Glycol
Simethicone Emulsion

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 12 months.

6.4 Special precautions for storage

Not applicable.

6.5 Nature and composition of immediate packaging

1L, 2.5L, 3L & 5L: White HDPE backpack containers with a
Blue polypropylene cap and an aluminium foil seal.
10 L: White HDPE container with a white HDPE cap and an aluminium foil seal.
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 containers. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

6. MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd
7 Rodney Street
Liverpool
L1 9HZ

7. MARKETING AUTHORISATION NUMBER

Vm 11990/4060

8. DATE OF FIRST AUTHORISATION

22 August 2017

9. DATE OF REVISION OF THE TEXT

March 2022

Approved 29 March 2022