A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Carton and/or Label for 1L, 2.5L, 3L, 5L and 10L}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albex Advance 200 mg/ml oral suspension for cattle.

Albendazole

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:

Albendazole	200.0 mg

Preservatives:

Methyl Parahydroxybenzoate (E218)	2.0 mg/ml
Propyl Parahydroxybenzoate	0.2 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

White to off white suspension

4. PACKAGE SIZE

1L

2.5 L

3 L

5 L

10 L

5. TARGET SPECIES

Cattle

6. 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
Approved for use in dairy cattle.
Controls Roundworms, Lungworms, Tapeworms, Adult Liver Fluke, Fluke and Roundworm Eggs.
Low volume Albendazole.

7. METHOD AND ROUTES OF ADMINISTRATION

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: 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.

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

8. WITHDRAWAL PERIODS

Meat and offal: 14 days.

Milk: 72 hours.

9. SPECIAL WARNING(S), IF NECESSARY

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 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 the results of the test(s) strongly suggest resistance to a particular anthelmintic, an 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

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

Special precautions for use in animals

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.

Not to be diluted or mixed with other products.

Avoid the introduction of contamination during use.

Adverse reactions (frequency and seriousness)

None known.

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.

Environmental properties

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

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.

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

Not applicable.

Incompatibilities

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

If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging: 12 months.

Once opened, use by ____

11. SPECIAL STORAGE CONDITIONS

Not applicable.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder and manufacturer responsible for batch release:
Chanelle Animal Health Ltd.
7 Rodney Street,
Liverpool L1 9HZ
UK

16. MARKETING AUTHORISATION NUMBER

Vm 11990/4060

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Approved 29 March 2022