LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE}
LABEL /Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albex 10% w/v Oral Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Oral suspension containing 10% w/v Albendazole

Excipients:

Methyl Parahydroxybenzoate E218	0.2% w/v
Propyl Parahydroxybenzoate	0.02% w/v
Green S E142	0.0018% w/v

1-BZ Albendazole belongs to the benzimidazole (1-Bz) class of anthelmintics.

3. PHARMACEUTICAL FORM

Oral suspension
A pale blue, free-flowing suspension.

4. PACKAGE SIZE

1L, 2.5L, 5L, 10 L

5. TARGET SPECIES

Cattle & Sheep

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake container before use.
For oral administration only. To ensure administration of correct dose, body weight should be determined as accurately as possible, accuracy of the dosing device should be checked.
1 ml of Albex 10% contains 100 mg Albendazole.

Cattle For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs, 7.5 mg albendazole per kg bodyweight which is equivalent to 7.5 ml Albex 10% per 100 kg bodyweight.
For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle, 10 mg albendazole per kg bodyweight, which is equivalent to 10 ml Albex 10% per 100 kg bodyweight.

Sheep: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs, 5 mg albendazole per kg bodyweight which is equivalent to 1.0 ml Albex 10% per 20 kg bodyweight. For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep, 7.5 mg albendazole per kg bodyweight, which is equivalent to 1.5 ml Albex 10% per 20 kg bodyweight.

Cattle			Sheep		
Bodyweight	Worm dose (7.5 mg/kg)	Fluke & worm dose (10 mg/kg)	Bodyweight	Worm dose (5.0 mg/kg)	Fluke & worm dose (7.5 mg/kg)
50 kg	3.75 ml	5.0 ml	Up to 10 kg	0.5 ml	0.75 ml
100 kg	7.50 ml	10.0 ml	11 - 20 kg	1.0 ml	1.50 ml
200 kg	15.00 ml	20.0 ml	21 - 30 kg	1.5 ml	2.25 ml
300 kg	22.50 ml	30.0 ml	31 - 40 kg	2.0 ml	3.00 ml
400 kg	30.00 ml	40.0 ml	41 - 50 kg	2.5 ml	3.75 ml
			51 - 60 kg	3.0 ml	4.50 ml
			61 - 70 kg	3.5 ml	5.25 ml
			71 - 80 kg	4.0 ml	6.00 ml

Cattle over 400 kg give a further 3.75 or 5 ml for each additional 50 kg bodyweight.
Sheep over 80 kg give a further 0.5 or 0.75 ml for each additional 10 kg bodyweight.

8. WITHDRAWAL PERIOD

Cattle may be slaughtered for human consumption only after 14 days from the last treatment. Sheep may be slaughtered for human consumption only after 5 days from the last treatment.
Animals must not be slaughtered for human consumption during treatment.

Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 60 hours from the last treatment. Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not dose ewes at the 'fluke and worm dose' (7.5 mg/kg) during tupping or for 1 month after removing the rams. Care must be taken not to damage the pharyngeal region, particularly in sheep, when dosing. Assess bodyweight as accurately as possible before calculating the dosage. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your Veterinary Surgeon.

The use of Albex 10% in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance. Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment.

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).
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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 has been reported in *Teladorsagia Haemonchus, Cooper* and *Trichostrongylus* species in small ruminants. 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.

For animal treatment only.
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.
Do not mix with other products.

Overdose: no treatment specified.

1-BZ Albendazole belongs to the benzimidazole (1-Bz) class of anthelmintics.

10. EXPIRY DATE

<EXP>

11. SPECIAL STORAGE CONDITIONS

N/A

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 product or used containers. Dispose of any unused product or containers in accordance with guidance from an appropriate waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR 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

MA Holder: Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, H62 FH90, Ireland

Manufacturer: Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/3022

POM-VPS

17. MANUFACTURER'S BATCH NUMBER

<BN> {number}

Gavin Hall
Approved: 11 September 2025