

LABELLING

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

{NATURE/TYPE}
LABEL and CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albex 2.5% SC w/v Oral Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Oral suspension containing 2.5% w/v Albendazole. Also contains Selenium (0.027% w/v) and Cobalt (0.063% w/v).

Excipients:

Methyl Parahydroxybenzoate E218	0.2% w/v
Propyl Parahydroxybenzoate	0.02% w/v
Copper chlorophyll complex sodium E141	0.23% w/v

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

3. PHARMACEUTICAL FORM

Oral suspension.
A pale green, free-flowing suspension.

4. PACKAGE SIZE

1L, 2.5L, 5L or 10L

5. TARGET SPECIES

Cattle & Sheep

6. INDICATION(S)

Albex 2.5% SC 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 sheep and cattle. The product is also ovicidal against fluke and roundworm eggs. The selenium and cobalt in this product are trace elements of use as nutritional supplements.

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*.

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*.

Albex 2.5% SC 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 a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. Estimate bodyweight accurately.

1 ml of Albex 2.5% SC contains 25 mg Albendazole. Each ml also contains 0.27 mg selenium (as sodium selenite and 0.63 mg cobalt (as cobalt sulphate).

Sheep: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs, 5 mg albendazole per kg bodyweight which is equivalent to 2.0 ml Albex 2.5% SC per 10 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 3 ml Albex 2.5% SC per 10 kg bodyweight.

Cattle For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs, 7.5 mg albendazole per kg bodyweight which is equivalent to 15 ml Albex 2.5% SC per 50 kg bodyweight. For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle, 10 mg albendazole per kg bodyweight, which is equivalent to 20 ml Albex 2.5% SC per 50 kg bodyweight.

Dosage Guide CATTLE		
Bodyweight	Worm dose (7.5 mg/kg)	Fluke & worm (10 mg/kg)
50 kg	15 ml	20 ml
100 kg	30 ml	40 ml
150 kg	45 ml	60 ml
200 kg	60 ml	80 ml
250 kg	75 ml	100 ml
300 kg	90 ml	120 ml
350 kg	105 ml	140 ml
400 kg	120 ml	160 ml

Dosage Guide SHEEP		
Bodyweight	Worm dose (5.0 mg/kg)	Fluke & worm (7.5 mg/kg)
Up to 10 kg	2 ml	3 ml
11 - 20 kg	4 ml	6 ml
21 - 30 kg	6 ml	9 ml
31 - 40 kg	8 ml	12 ml
41 - 50 kg	10 ml	15 ml
51 - 60 kg	12 ml	18 ml
61 - 70 kg	14 ml	21 ml
71 - 80 kg	16 ml	24 ml

Cattle over 400 kg - give a further 15 or 20 ml for each additional 50 kg bodyweight.

Sheep over 80 kg - give an additional 2 or 3 ml for each additional 10 kg bodyweight.

8. WITHDRAWAL PERIOD

Animals may not be slaughtered for human consumption during treatment.

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. Milk for human consumption may be taken from cows only after 60 hours from the last treatment.

Milk for human consumption may not be taken during 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.

Assess bodyweight as accurately as possible before calculating the dosage. Care must be taken not to damage the pharyngeal region, particularly in sheep, when dosing.

Do not administer other cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary surgeon.

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 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*, *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.

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, wash the affected area with soap and water.

If irritation persists, seek medical attention.

Do not mix with other products.

Selenium and cobalt are included in Albex 2.5% SC as nutritional supplements and are not intended to be used therapeutically. Administration of ionophores to lambs has been shown to enhance selenium bioavailability. Concurrent administration of

ionophores and Albex 2.5% SC may therefore lead to an increased risk of selenium toxicity.

The use of Albex 2.5% SC in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance. The product should only be used in areas where deficiencies of selenium and cobalt are likely to occur. In cases of doubt, consult a veterinary surgeon. Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment.

10. EXPIRY DATE

EXP mm/yy

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 the product or used container. Dispose of any unused product and empty containers in accordance with guidance from your local 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 08749/5060
Legal Category

POM-VPS

17. MANUFACTURER'S BATCH NUMBER

<BN>

Gavin Hall
Approved: 11 September 2025