MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALBACERT 2.5% w/v SC Oral Suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

1 ml of Albacert 2.5% w/v SC contains 25 mg Albendazole.

Each ml also contains 0.27 mg selenium (as sodium selenite) and 0.63 mg cobalt (as cobalt sulphate).

4. PHARMACEUTICAL FORM

Oral suspension

5. PACKAGE SIZE

High density polyethylene jerricans with high density polyethylene screw-fit, tamper evident closures and expanded polyethylene liners containing 1 L, 2.5 L, 5 L or 10 L of product.
High density polyethylene flexipack containers with screw-fit closures, and aluminium foil sealed polyfaced steran liners containing 1 L, 2.5 L or 5 L of product.

6. INDICATION(S)

Albacert 2.5% w/v 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, Trichostronglus, 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.*

Albacert 2.5% w/v SC *is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.*

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

9. TARGET SPECIES

Cattle and Sheep

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

DOSAGE GUIDE: Sheep over 80 kg - give an additional 2 or 3ml for each additional 10 kg bodyweight. Cattle over 400 kg - give a further 15 or 20 ml for each additional 50 kg bodyweight.

Shake container before use.
• For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately before calculating correct dosage.
• 1 ml of Albacert 2.5% w/v 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 Albacert 2.5% w/v SC per 10kg 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 Albacert 2.5% w/v 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 Albacert 2.5% w/v 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 Albacert 2.5% w/v SC per 50 kg bodyweight.

11. ADVICE ON CORRECT ADMINISTRATION

See dosing tables on label

12. WITHDRAWAL PERIOD

Cattle: Meat & Offal: 14 days
Milk: 60 hours

Sheep: Meat & Offal: 5 days.
Not to be used in sheep producing milk for human consumption.

13. SPECIAL STORAGE PRECAUTIONS

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

14. SPECIAL WARNING(S)

User Warnings: Wash hands after use. Avoid direct contact with the product. Wear suitable 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 affected area with soap and water. If irritation persists, seek medical attention.

CONTRA-INDICATIONS, WARNINGS AND PRECAUTIONS:
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.

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 belonging to another pharmacological class and having a different mode of action should be used. Resistance to benzimadazoles (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.

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.

15. EXPIRY DATE

16. 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. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

17. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

POM-VPS

For animal treatment only

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

20. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/5106

21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION

Further Information: Selenium and cobalt are included in **Albacert 2.5% w/v 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 **Albacert 2.5% w/v SC** may therefore lead to an increased risk of selenium toxicity. The use of **Albacert 2.5% w/v 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. This veterinary medicinal product does not require any special storage conditions.

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

Gavin Hall
Approved: 01 October 2025