

**MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO
PACKAGE LEAFLET,**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac Limited

Woolpit Business Park

Windmill Avenue

Woolpit

Bury St Edmunds

Suffolk

IP30 9UP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albenil SC 25mg/mL Oral Suspension

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

Albendazole 25mg/mL

Selenium (as sodium selenite) 0.27mg/mL

Cobalt (as cobalt sulfate) 0.63mg/mL

Methyl parahydroxybenzoate E218 2 mg/ml

Propyl parahydroxybenzoate 0.2 mg/ml

4. PHARMACEUTICAL FORM

Oral suspension

5. PACKAGE SIZE

2.5 litre and 10 litre

6. INDICATION(S)

Albenil SC is a broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult live fluke in sheep and cattle.

Albenil SC 25mg/ml is ovicidal against fluke and roundworm eggs. The selenium and cobalt in this product are trace elements of use as nutritional supplements.

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*.

Albenil 25 mg/ml SC ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

7. CONTRAINDICATIONS

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 or 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 a different 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.

8. ADVERSE REACTIONS

None known

9. TARGET SPECIES

Cattle and sheep

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

For oral administration.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Cattle:

For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs, 7.5 mg albendazole per kg bodyweight which is equivalent to 15ml Albenil SC 25 mg/ml 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 20ml Albenil SC 25 mg/ml per 50 kg bodyweight.

Sheep:

For the control of roundworms, lungworms, tapeworms, fluke and roundworm eggs, 5 mg albendazole per kg bodyweight which is equivalent to 2.0 ml Albenil SC 25 mg/ml 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 Albenil SC 25 mg/ml per 10kg bodyweight

Do not mix with other products.

11. ADVICE ON CORRECT ADMINISTRATION

SHAKE THE CONTAINER BEFORE USE. For oral administration. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. Estimate bodyweight accurately.

Dosage Tables

Cattle		
Bodyweight	Worm Dose (7.5 mg/kg)	Fluke and Worm Dose (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

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

Sheep		
Bodyweight	Worm Dose (5.0 mg/kg)	Fluke and Worm Dose (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

Sheep over 80 kg – give a additional 2 ml or 3 ml for each additional 10 kg bodyweight.

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>

For animal treatment only. Keep out of the reach and sight of children.

Wash hands after use. Avoid skin and eye contact with the product.

Wear suitable protective clothing, including impermeable rubber gloves, whilst administering the product. 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.

Selenium and cobalt are included in Albenil SC 25 mg/ml 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 Albenil 2.5% SC may therefore lead to an increased risk of selenium toxicity.

The use of Albenil SC 25mg/ml 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. Cattle suffering

1-BZ

from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment.

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

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. DATE ON WHICH THE LABEL WAS LAST APPROVED

April 2015

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

(see under section 14)

POM-VPS

To be supplied only on veterinary prescription

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

(see under section 14)

20. MARKETING AUTHORISATION NUMBER(S)

Vm 11188/4013

21. MANUFACTURER'S BATCH NUMBER

<22. OTHER INFORMATION>

None

Approved: 05/06/2017

