

PARTICULARS TO APPEAR ON THE OUTER PACKAGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albensure 10% w/v Oral Suspension
Fluke and Worm drench for Cattle and Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Albensure 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.

3. PHARMACEUTICAL FORM

Oral suspension containing 10% w/v Albendazole

4. PACKAGE SIZE

2.5 litres

5. TARGET SPECIES

Cattle and Sheep

6. INDICATION(S)

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: *Teladorsagia* (*Ostertagia*), *Haemonchus*, *Trichostrongylus*, *Nematodirus* (including *N. battus*), *Chabertia* and *Oesophagostomum*. It is usually effective against inhibited larvae of *Ostertagia*.

Lungworms: *Dictyocaulus filarial*

Tapeworms: *Moniezia* spp

Adult liver fluke: *Fasciola hepatica*

ALBENSURE 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 using properly calibrated dosing equipment. Estimate bodyweight accurately 1ml of Albensure 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 Albensure 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 Albensure 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 Albensure 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 Albensure 10% per 20 kg bodyweight.

CATTLE			SHEEP		
Bodyweight	Worm dose (7.5 mg/kg)	Fluke & worm (10 mg/kg)	Bodyweight	Worm dose (5.0 mg/kg)	Fluke & worm (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
 To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

8. WITHDRAWAL PERIOD

Animals must 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 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 aht the 'fluke and worm dose' (7.5 mg/kg) during tuppig or for 1 month after removing the rams. Car 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 and extended period of time
- Underdosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device (if any)

To reduce this risk, dosing programmes should be discussed with your Veterinary Surgeon. Not to be diluted. Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (eg 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.

Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use. 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.

DO NOT MIX WITH OTHER PRODUCTS

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC 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

POM-
VPS

To be supplied only on veterinary prescription For animal treatment only

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4039

17. MANUFACTURER’S BATCH NUMBER

18. FURTHER INFORMATION

The use of Albensure 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.

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

Albensure 10% also contains 0.2% w/v Methyl Hydroxybenzoate, 0.02% w/v Propyl Hydroxybenzoate and 0.0018% w/v, Green S, E 142

Approved: 16/04/2018

