SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albensure 10% w/v Oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	
Albendazole	10% w/v

Excipients	
Green S (E142)	0.0018% w/v
Methyl parahydroxybenzoate	0.2% w/v
Propyl parahydroxybenzoate	0.02% w/v

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension
A pale blue, free flowing oral suspension

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep

4.2 Indications for use, specifying the target species

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: *Teladorsagia (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*.

The product is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

4.3 Contra-indications

Known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

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 bodyweight, 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, 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

4.5 Special precautions for use.

i. Special precautions for use in animal**s**

Not to be diluted or mixed with other products.
Avoid the introduction of contamination during use.
Care must be taken not to damage the pharyngeal region during dosing, particularly in sheep. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce the risk, dosing programmes should be discussed with a veterinary surgeon.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Direct contact with the skin should be kept to a minimum. 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 affected area with soap and water. If irritation persists, seek medical advice. Wash hands after use.

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Do not dose ewes at the 'fluke and worm' dose rate, (7.5 mg/kg), during tupping or for 1 month after removing the rams. Albensure 10% can be safely used during lactation. The use of the product in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked
For oral administration only.
Do not mix with other products.

One ml of Albensure 10% Suspension contains 100mg/ml albendazole

Cattle:
Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs.
Dosage: 7.5 mg albendazole per kg bodyweight.
Fluke and worm dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle.
Dosage: 10 mg albendazole per kg bodyweight.

Sheep:
Worm dose: For the control of roundworms, lungworms, tapeworms, fluke and roundworm eggs.
Dosage: 5 mg albendazole per kg bodyweight.

Fluke and Worm Dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep.
Dosage: 7.5 mg albendazole per kg bodyweight.

4.10 Overdose (symptoms, emergency procedures, antidotes)

Benzimidazoles have a wide margin of safety.

4.11 Withdrawal period for the various foodstuffs, including those for which the withdrawal period is zero

Cattle (meat and offal):	14 days
Cattle (milk):	60 hours
Sheep (meat):	5 days

Not to be used in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATCvet Code QP52AC11

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.

5.2 Pharmacokinetic particulars

Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in the absence of microtubules in the intestinal cells of the nematode, with the result that these cells cannot absorb nutrients, thus causing a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, resulting in the preferential toxicity of albendazole to the helminth and not to the host. Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Green S (E142)
Citric acid monohydrate
Sodium citrate
Xanthan Gum
Povidone 90
Polysorbate 20
Propylene glycol
Simethicone
Water, purified

6.2 Incompatibilities (major)

None known

6.3 Shelf-life, when necessary after reconstitution of the product, or when the immediate packaging is opened for the first time

Shelf life of the veterinary medicinal product as packaged for sale:
3 Years

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of immediate packaging

High density polyethylene bottles (jerricans) with high density polyethylene closure (screw fit) with expanded polyethylene liners containing 2.5L of product.

High density polyethylene flexipack containers with polypropylene homopolymer closure (screw fit) with aluminium foil seal and polyfaced steran liner containing 2.5L of product.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used containers.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals
Manufacturing Ltd.
Loughrea
Co Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/4039

9. DATE OF RENEWAL OF THE AUTHORISATION

Date of Renewal: 8th May 2009

10. DATE OF THE REVISION OF THE TEXT

July 2013

APPROVED T. NASH **3/07/13**