1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alphalben 100 mg/ml Oral Suspension for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Albendazole 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	10 mg
Carbomer 971P	
Polysorbate 80	
Propylene glycol	
Sodium hydroxide	
Vanillin	
Water, purified	

A white, free-flowing suspension.

3. CLINICAL INFORMATION

3.1. Target species

Cattle and sheep

3.2 Indications for use for each target species

For the treatment of infections caused by gastrointestinal roundworms, lungworms, tapeworms and adult flukes in cattle and sheep, if the parasite is sentitive to albendazole.

Gastrointestinal roundworms: *Haemonchus spp., Ostertagia spp., Trichostrongylus spp., Bunostomum spp., Cooperia spp., Nematodirus spp., Chabertia spp., Oesophagostomum spp., Toxocara spp.*
Lungworms: *Dictyocaulus spp.*
Tapeworms: *Moniezia spp.*
Adult flukes: *Fasciola hepatica, Dicrocoelium dendriticum*.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in case of known resistance to albendazole or other benzimidazols.
Do not use in acute fasciolosis caused by the immature forms of *Fasciola hepatica.*

3.4 Special warnings

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. Therefore, the use of this veterinary medicinal 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.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce the risk, dosing programmes should be discussed with a 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 veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Care must be taken not to damage the pharyngeal region when dosing, particularly in sheep.
Animals within one group should be treated at the same time.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
Avoid skin and eye contact with the veterinary medicinal product.
Wear suitable protective clothing, including impermeable rubber gloves, whilst administering the veterinary medicinal product.
In case of accidental eye exposure, flush eye thoroughly with running water. If irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of accidental skin exposure, wash the affected area with soap and water. If irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
The veterinary medicinal product should not be administered by pregnant women.
People with known hypersensitivity to benzimidazoles should avoid contact with the veterinary medicinal product.
Do not eat, drink or smoke when handling the veterinary medicinal product.

Special precautions for the protection of the environment:
DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or used container.
Albendazole should not enter soil as this may be dangerous for earthworms and other terrestrial organisms. Manure containing the active substance should not be spread on the same area of land in successive years to avoid accumulation of albendazole which may cause adverse effects in the terrestrial environment. Very persistent.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Other precautions:

The long-term effects of the veterinary medicinal product on the population dynamics of dung beetles have been investigated. Therefore, it is advisable not to treat animals on the same pasture every season. Animals should not be allowed out of the stable for at least 5 days after the application in order to prevent excretion on pasture.
Manure from treated animals must be stored for 4 months prior to spreading and must be left for at least 2 days before incorporating into soil to allow further degradation of albendazole and its metabolites. Rotational pasture management with other livestock species should be used.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not dose during the first trimester of pregnancy. Use only accordingly to the benefit-risk assessment by the responsible veterinarian during last two parts of pregnancy and during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
Shake well before use.

Cattle:
For the treatment of infections caused by gastrointestinal roundworms, lungworms and tapeworms: 7.5 mg albendazole per kg b.w. (7.5 ml veterinary medicinal product/ 100 kg b.w.).
For the treatment of infections caused by *Fasciola hepatica* and *Dicrocoelium dendriticum* or in case of Type 2 ostertagiosis: 10 mg albendazole per kg b.w. (10 ml veterinary medicinal product/ 100 kg b.w.)

Sheep:
For the treatment of infections caused by gastrointestinal roundworms, lungworms, and tapeworms:
5 mg albendazole per kg b.w. (0.5 ml veterinary medicinal product/ 10 kg b.w.).
For the treatment of infections caused by *Fasciola hepatica* and *Dicrocoelium dendriticum*: 7.5 mg albendazole per kg b.w. (0.75 ml veterinary medicinal product/ 10 kg b.w.)

To ensurea correct a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under – or overdosing.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The therapeutic index of albendazole is high. Three or five times overdose does not cause clinical signs. In case of serious overdose the animals should be treated symptomatically.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 14 days
Milk: 5 days

Sheep:
Meat and offal: 14 days
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC11

4.2 Pharmacodynamics

The veterinary medicinal product is a broad spectrum anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms and adult flukes in cattle and sheep. The veterinary medicinal product is also ovicidal against fluke and roundworm eggs. Albendazole 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. Albendazole has also been shown to inhibit the fumarate reductase system of helminths and impair energy production and intestinal glucose resorption.

4.3 Pharmacokinetics

Albendazole has poor water solubility and limited absorption from the gastrointestinal tract (about 50% of the oral dose is absorbed in cattle). Following absorption, there is rapid first pass metabolism in the liver and the sulphide moiety of albendazole is oxidised to the pharmacologically active sulphoxide, then to the sulphone, followed by deacetylation of the carbamate group to form the 2-aminosulphone.

Environmental properties
DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or used container.
Albendazole should not enter soil as this may be dangerous for earthworms and other terrestrial organisms. Manure containing the active substance should not be spread on the same area of land in successive years to avoid accumulation of albendazole which may cause adverse effects in the terrestrial environment. Very persistent.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

Pack sizes: 1 litre / 5 litre in polypropylene bottle closed with polypropylene screw cap. The cap is assembled with a seal disc, an induction closuring disc with red safety ring for the 1 literpack size).

Not all pack sizes may be marketed in all markets.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as albendazole may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

ALPHAVET Zrt.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10391/001/001

8. DATE OF FIRST AUTHORISATION

16/02/2018

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

27/08/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).