SUMMARY OF PRODUCT CHARACTERISTICS

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:

Benzyl alcohol (E1519)	10 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension
A white, free-flowing suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep

4.2 Indications for use, specifying the 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.*

4.3 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.*

4.4 Special warnings for each target species

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 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 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.

4.5 Special precautions for use

Special precautions for use in animals

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 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.

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 product.

Other precautions

The long-term effects of the veterinary medicinal product on the population dynamics of dung beetles have not 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration.
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 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 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 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 product/ 10 kg b.w.)

To ensure administration of 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

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

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Benzimidazoles and related substances; Albendazole.
ATCvet code: QP52AC11

5.1 Pharmacodynamic properties

The 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 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 971P
Polysorbate 80
Propylene glycol
Sodium hydroxide
Vanillin
Benzyl alcohol (E1519)
Water, purified

6.2 Major incompatibilities

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

6.3 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.

6.4. Special precautions for storage

Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

1 litre in polypropylene bottle closed with polypropylene screw cap. The cap is assembled with a seal disc, an induction closuring disc and a red safety ring.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 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.
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

ALPHAVET Zrt.
H-1194 Budapest, Hofherr A. u. 42.
Hungary
Tel: +36-22-516-416
Fax: +36-22-516-419
E-mail: alpha-vet@alpha-vet.hu

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1 L polypropylene bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alphalben 100 mg/ml Oral Suspension for Cattle and Sheep
Albendazole

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Albendazole 100 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

1 litre

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Shake well before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods
Cattle:
Meat and offals: 14 days
Milk: 5 days

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf life after first opening the immediate packaging: 28 days
Once opened use by:

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

ALPHAVET Zrt.
Hofherr A. u. 42., Budapest, H-1194, Hungary

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET (concertina leaflet sticked to the immediate package)
Alphalben 100 mg/ml Oral Suspension for Cattle and Sheep

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

Marketing authorisation holder:
ALPHAVET Zrt.
Hofherr A. u. 42., Budapest, H-1194, Hungary

Manufacturer responsible for batch release:
ALPHAVET Zrt.
Dr. Köves János út 13., Bábolna, H-2943, Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alphalben 100 mg/ml Oral Suspension for Cattle and Sheep
Albendazole

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

Each ml of white or almost white homogenous, free-flowing suspension contains:

Active substance:

Albendazole: 100 mg

Excipients:
Benzyl alcohol (E1519): 10 mg

4. INDICATION(S)

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.*

5. 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.*

6. ADVERSE REACTIONS

No adverse reactions were observed after recommended dosage.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and sheep

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

For oral administration.

Cattle:
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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 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 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 product/ 10 kg b.w.)

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

To ensure administration of 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.

10. WITHDRAWAL PERIOD(S)

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

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not refrigerate or freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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 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.

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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:

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- 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.

Special precautions for use in animals:

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 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.

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 product.

Other precautions

The long-term effects of the veterinary medicinal product on the population dynamics of dung beetles have not 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.

Use during 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.

Overdose (symptoms, emergency procedures, 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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Available package size:
1 litre