SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Allverm 4% Oral Suspension for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	% w/v
Albendazole oxide (ricobendazole)	*4.00*
Other ingredients	
Cobalt sulphate (heptahydrate) [equivalent to 0.377% w/v elemental cobalt]	2.88
Sodium selenate (anhydrous) [equivalent to 0.041% w/v elemental selenium]	0.154
Antimicrobial preservatives:	
Methyl parahydroxybenzoate	0.15
Propyl parahydroxybenzoate	0.015
Sodium Metabisulphate	0.10

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension
A pink coloured aqueous oral suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep

4.2 Indications for use, specifying the target species

Broad spectrum worm and fluke drench;

For the control of adult and larval stages of benzimidazole-sensitive gastro-intestinal roundworms (*Bunostomum, Chabertia, Cooperia, Haemonchus, Nematodirus, Oesophagostomum, Ostertagia, Strongyloides* and *Trichostrongylus*), tapeworms (*Moniezia*) and lungworms (*Dictyocaulus filaria*), and for the control of adult liver fluke *(Fasciola hepatica)* and the treatment of chronic, but not acute, fascioliasis in sheep

Ovicidal to round worm eggs

Also aids in the prevention of cobalt and selenium deficiency.

4.3 Contraindications

Ewes should not be treated at the fluke and worm dose during tupping and until one month after the tups are removed.

Not recommended for use in cattle.

4.4 Special warnings for each target species

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
Under dosing, 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 another pharmacological class and having a different mode of action should be used.

Resistance to benzimidazoles has been reported in *Teladorsagia, Haemonchus, Cooperia* and *Trichostrongylus* species in small ruminants. 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 animals

For oral administration only
Shake container well before use.
The product should only be used in areas known to be deficient in cobalt and selenium. Do not administer other cobalt and selenium supplements concurrently unless specifically advised by your vet.
If in doubt, consult a veterinary surgeon.
Not to be diluted.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use.
Avoid direct contact with 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.

4.6 Adverse reactions (frequency and seriousness)

Frequent use or misuse of anthelmintics may enhance the development of resistance. If unsure of the resistance status of worms on your property, consult your veterinary surgeon for advice on conducting a resistance test.

4.7 Use during pregnancy, lactation or lay

Care should be taken not to exceed the recommended dose, especially during the first month of pregnancy.

Ewes should not be treated at the fluke and worm dose during tupping and until one month after the tups are removed.

Ensure careful handling of ewes if used near lambing time.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Do not mix with other products.

Administer orally using standard drenching equipment.

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

Use the dose volume appropriate to the heaviest animals when treating on a group basis.

Worm Dose:

Dosage: 5mg albendazole oxide* per kg bodyweight (1ml per 8kg bodyweight). The dosage rates of trace elements are 0.75mg cobalt per kg and 0.08mg selenium per kg bodyweight.

Bodyweight	Dosage	Doses per litre
Up to 16kg	2 ml	500
17–24kg	3 ml	333
25–32kg	4 ml	250
33–40kg	5ml	200
41–48kg	6 ml	166
49-56kg	7 ml	142
57-64kg	8 ml	125
65-72kg	9 ml	111
73-80kg	10 ml	100
Over 80kg	12 ml	83

Dosing Programme:

Ewes and gimmers
Dose ewes 2-6 weeks before lambing and again soon after lambing. On heavily stocked pastures, treatment at intervals of 3-4 weeks may be necessary until autumn. Otherwise treat prior to tupping and at housing

Lambs and hoggs
Lambs at risk from Nematodirus infection require dosing at 2 week intervals. Otherwise treat lambs from 4-6 weeks of age and hoggs from late May at 3 week intervals until autumn. Dose at weaning and move to clean pasture. If clean pasture is unavailable, dose at 3-4 week intervals until sold, or until early winter.

Treat all bought-in sheep before allowing to mix with the flock. (N.B. Most independent advice recommends the use of an avermectin (3-AV) containing product at this time).

Fluke and Worm Dose:

Dosage: 7.5mg albendazole oxide* per kg bodyweight (1ml per 5.33kg bodyweight). The dosage rates of trace elements are 1.125mg cobalt per kg and 0.12mg selenium per kg bodyweight.

Bodyweight	Dosage	Doses per litre
Up to 16kg	3 ml	333
17–24kg	4.5 ml	222
25–32kg	6 ml	166
33–40kg	7.5ml	133
41–48kg	9 ml	111
49-56kg	10.5 ml	95
57-64kg	12 ml	83
65-72kg	13.5 ml	74
Over 72kg	16 ml	62

Dosing Programme:

Dose all ewes 2-6 weeks before and soon after lambing to reduce pasture contamination with roundworm eggs and control chronic fluke disease.
Dose all sheep in October/November and repeat at 4-6 week intervals until spring for outwintered stock.

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

The therapeutic margin for this product is high and problems due to overdosage are therefore unlikely.

4.11 Withdrawal period(s)

Sheep: Meat: 3 days

Milk: Not for use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic products, insecticides and repellents. Anthelmintics, Benzimidazoles and related substances

ATC vet code QP52AC11

5.1 Pharmacodynamic properties

Albendazole oxide (ricobendazole) is an anthelmintic belonging to the benzimidazole group. Its mode of action, in common with other benzimidazoles is the disruption of microtubule formation by extensive binding to nematode tubulin. It is active against larval and adult stages and is ovicidal.

5.2 Pharmacokinetic particulars

Albendazole oxide is slowly metabolised to a range of metabolites by hydroxylation, oxidation to sulphones, deacetylation to form amines and reduction to negligible amounts of albendazole. The most important metabolites are the sulphone and the 2-amino sulphone, neither of which is anthelmintically active.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Sodium Metabisulphate
Cobalt Sulphate (heptahydrate)
Sodium Selenate (anhydrous)
Propylene Glycol
Xanthan Gum
Aluminium Magnesium Silicate
Sorbitan Monolaurate
Polysorbate 80
Simeticone
Di-Sodium Phosphate Dihydrate
Citric Acid Monohydrate
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4. Special precautions for storage

Store in tightly closed original container in a safe place
Do not store above 25°C. Do not freeze.
Store away from food, drink and animal feedingstuffs

6.5 Nature and composition of immediate packaging

A pink coloured aqueous suspension contained within a natural (translucent), high density polyethylene flexi-pack of 1, 2.5 or 5 litre capacity, closed with a white, polypropylene, screw cap and ethylene ionomer coated foil induction seal.
OR
White high density polyethylene backpacks containing 0.8, 2.2 or 5 litre closed with a screw fit blue polypropylene cap.

Not all pack sizes may be marketed.

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

HARMFUL 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

Novartis Animal Health UK Limited
Frimley Business Park
Frimley
Camberley
Surrey
GU16 7SR
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

Vm 12501/4084

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 18th January 1990 / Renewal: 26th July 2005

10. DATE OF REVISION OF THE TEXT

June 2010