SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VALBAZEN™ SC 2.5 % Total Spectrum Wormer Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:	***% w/v***
Albendazole	2.50

For the full list of all other excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep.

4.2 Indications for use, specifying the target species

For the control of benzimidazole susceptible mature and developing immature forms of the following internal parasites of sheep;

Gastro-intestinal roundworms: *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus (including N battus), Chabertia and Oesophagostomum spp*.
Lungworms: *Dictyocaulus filaria*.
For the control of tapeworms: *Moniezia* spp.
For the control of adult liver flukes: *Fasciola hepatica*.

It is usually effective against inhibited larvae of benzimidazole susceptible *Ostertagia*.
Also kills nematode and fluke eggs.

4.3 Contraindications

Do not dose ewes at the ‘fluke and worm’ dose rate (7.5 mg/kg) during tupping and for 1 month after removing rams.
The product is not recommended for the treatment of acute fascioliasis.
The product is not recommended for use in cattle.

4.4 Special warnings for each target species

The product should only be used in areas where deficiencies of selenium and cobalt are likely to occur. In cases of doubt, consult your veterinary surgeon.
Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your 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 bodyweight, misadministration of the product or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance 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. 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

Do not administer at the same time as other products containing cobalt and selenium unless specifically advised by your vet.
Do not dilute.

ii. Special precautions to be taken by 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.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Side effects are not to be expected following treatment.

4.7 Use during pregnancy, lactation or lay

The product must not be used in sheep producing milk for human consumption.
Care should be taken not to exceed the worm dose rate during the first month of pregnancy.
The use of Valbazen in breeding rams 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

The product is given as an oral drench and is suitable for use with most types of automatic drenching equipment.
To ensure administration of the correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Do not mix with other products.
No special control of diet is necessary before or after treatment.

Note: Each ml of product will provide 0.27 mg of elemental selenium and 0.63 mg of elemental cobalt.

Worm dose:
Approximately 5 mg albendazole per kg bodyweight.
Dosage guide: 2ml per 10kg bodyweight.

Bodyweight (kg)	Dose (ml)
Up to 10	2
11 to 20	4
21 to 30	6
31 to 40	8
41 to 50	10
51 to 60	12
61 to 70	14

For sheep over 70 kg give a further 2 ml for each additional 10 kg bodyweight.

Fluke and worm dose:
Approximately 7.5 mg albendazole per kg bodyweight.
Dosage guide: 3 ml per 10 kg bodyweight.

Bodyweight (kg)	Dose (ml)
Up to 10	3
11 to 20	6
21 to 30	9
31 to 40	12
41 to 50	15
51 to 60	18
61 to 70	21

For sheep over 70 kg give a further 3 ml for each additional 10 kg bodyweight.

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

Moderate overdosage is unlikely to cause adverse reactions in healthy animals, but note Sections 4.3 and 4.7.

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment.
Sheep may be slaughtered for human consumption only after 8 days from the last treatment.
The product is contra-indicated for use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Albendazole is a broad-spectrum anthelmintic.
Selenium and cobalt are included in this product as nutritional supplements and are not intended to be used therapeutically.

Mechanism of action:
Although not all aspects of the mode of action of benzimidazoles are known, there is evidence to suggest that three mechanisms are involved:

- Inhibition of microtubule polymerisation
- Inhibition of intestinal glucose resorption
- Inhibition of fumarate reductase

Pharmacokinetics of albendazole:
The pharmacokinetics of albendazole have been extensively studied in both the target species (sheep) as well as in laboratory animals (mice and rats) and in humans for comparative purposes.

A number of general characteristic pharmacokinetic features have arisen from these studies:

- Elimination from the tissues is rapid, no retention in deep compartments of the body has been described.
- There is an enterohepatic cycle, but its effect on the rate of elimination from tissues seems to be quantitatively minor.
- Following oral administration, benzimidazoles are always extensively metabolised by mammals.
- Metabolites from oxidation and hydrolysis, which are more soluble than the parent molecule, prevail in blood, tissues, bile and urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Selenate Anhydrous (equivalent to 0.27 mg/ml elemental Selenium)
Cobalt Sulphate Heptahydrate (equivalent to 0.63 mg/ml elemental Cobalt)
Aluminium Magnesium Silicate
Carmellose Sodium 7H 3SF
Glycerol
Polysorbate 80
Sorbitan Monolaurate
Potassium Sorbate
Benzoic Acid
Antifoam 1510 (Dow Corning)
Tartrazine (E102)
Acid Brilliant Green BS (E142)
Water Purified

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

Do not store above 25°C.
Shake container before use.

6.5 Nature and composition of immediate packaging

1, 2.5, 5 and 10 litre plastic containers. 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, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty containers.

7. MARKETING AUTHORISATION HOLDER

Elanco Animal Health
Eli Lilly & Company Limited
Lilly House
Priestly Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00006/4126

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th June 2003

10. DATE OF REVISION OF THE TEXT

January 2011