1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Valbazen 100 mg/ml Total Spectrum Wormer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance	
Albendazole	100 mg

Excipients	
Potassium sorbate	1.5 mg
Benzoic acid	1.8 mg
Acid Brilliant Green (E142)	0.026 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension. A pale blue aqueous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and 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 cattle and sheep.

Cattle

Gastro-intestinal roundworms: *Ostertagia, Chabertia, Cooperia, Trichostrongylus, Nematodirus, Haemonchus, Bunostomum, Oesophagostomum and Strongyloides spp*.
Lungworms: *Dictyocaulus viviparus*

Sheep

Gastro-intestinal roundworms: *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus (including N battus), Chabertia and Oesophagostomum spp*.
Lungworms : *Dictyocaulus filaria*

For the control of tapeworms, *Monieziaspp*, in cattle and sheep.
For the control of adult liver flukes, *Fasciolahepatica*, in cattle and sheep.
In cattle it is usually effective against inhibited larvae of *Cooperia*and *Ostertagia*.

In sheep it is usually effective against inhibited larvae of benzimidazole susceptible *Ostertagia*.

The product is ovicidal.

4.3 Contraindications

Do not use in sheep producing milk for human consumption.
Do not dose ewes at the 'fluke and worm' dose rate (7.5 mg/kg) during tupping and for 1 month after removing rams.Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Where a dosing gun is used, care must be taken to avoid causing injury to the mouth and pharynx when dosing lambs and sheep.
Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment.
Valbazen is not recommended for the treatment of acute fascioliasis in sheep.

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

4.5 Special precautions for use

Special precautions for use in animals

Intensive use or mis-use of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

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 use of Valbazen in pregnant cattle or breeding bulls or rams is not expected to interfere with their reproductive performance. Care should be taken not to exceed the worm dose rate during the first month of pregnancy in ewes and the fluke and worm dose during the first month of pregnancy in cows. The product must not be used in sheep producing milk for human consumption.

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.
A suitably graduated drenching gun should be used, in line with the low dose volume to be used in sheep.
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.

No special control of diet is necessary before or after treatment.

CATTLE

Worm dose
Approximately 7.5 mg albendazole per kg bodyweight.

Dosage guide: 3.75 ml per 50 kg bodyweight.

Bodyweight (kg)	Dose (ml)
100	7.5
200	15.0
300	22.5

400	30.0
Over 400 kg	Give a further 3.75 ml for each additional 50 kg bodyweight.

Fluke and worm dose:
Approximately 10 mg albendazole per kg bodyweight.
Dosage guide: 5 ml per 50 kg bodyweight.

Bodyweight (kg)	Dose (ml)
100	10
200	20
300	30
400	40
Over 400 kg	Give a further 5 ml for each additional 50 kg bodyweight

SHEEP

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

Bodyweight (kg)	Dose (ml)
Up to 10	0.5
11 to 20	1.0
21 to 30	1.5
31 to 40	2.0
41 to 50	2.5
51 to 60	3.0
61 to 70	3.5
Over 70 kg	Give a further 0.5 ml for each additional 10 kg bodyweight

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

Bodyweight (kg)	Dose (ml)
Up to 10	0.75
11 to 20	1.50
21 to 30	2.25
31 to 40	3.00
41 to 50	3.75
51 to 60	4.50
61 to 70	5.25
Over 70 kg	Give a further 0.75 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.
Cattle may be slaughtered for human consumption only after 14 days from the last treatment.
Sheep may be slaughtered for human consumption only after 10 days from the last treatment.
Milk for human consumption must not be taken during treatment.
Milk for human consumption may be taken from cows only after 72 hours from the last treatment.The product is contra-indicated for use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

The pharmacokinetics of albendazole have been extensively studied in both the target species (cattle and 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 enterohepathic 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

Aluminium magnesium silicate
Sodium Carboxymethylcellulose
Polysorbate 80
Sorbitan Laurate
Potassium Sorbate
Antifoam 1510
Benzoic Acid
Glycerol
Acid brilliant green (E142)Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

500 ml, 1 litre, 2.5 litre and 5 litre translucent white high density polyethylene containers with polypropylene screw caps.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

Unused product or waste material should be disposed of in accordance with the current practice for pharmaceutical waste under national waste disposal regulations

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co Dublin
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/081/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1994
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

September 2017