1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Albencare with Selenium Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Albendazole150.0 mg

Excipients

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Selenium (as sodium selenate)	1.5 mg
Potassium sorbate	1.8 mg
Formaldehyde solution 35%	2.0 mg
Anhydrous citric acid	
Colloidal anhydrous silica	
Formaldehyde solution 35%	
Monopropylene glycol	
Macrogol 6000	
Polyoxyl 40 stearate	
Potassium sorbate	
Xanthan gum	
Purified water	

Oral suspension.
An off-white, creamy suspension.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle and calves.

3.2 Indications for use, for each target species

Effective against benzimidazole sensitive mature and immature roundworms, including Type II ostertagia, lungworms, tapeworms and adult liver fluke in cattle.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.

3.4 Special warnings

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.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species

Not applicable.

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

Avoid direct contact with the skin and eyes. In case of accidental spillage, wash the affected area immediately with clean running water.
Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product. Wash hands after use.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy. See also SPC section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use at the same time as any other selenium containing product without consulting a veterinarian.

3.9 Administration routes and dosage

Oral use.

Shake well before use.
Using standard drenching equipment administer orally.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Cattle:
Worm infestations - 7.5 mg albendazole per kg bodyweight (0.75 ml per 15 kg bodyweight). This dose also delivers 0.073 mg per kg Selenium.
Worm and fluke infestations - 10 mg albendazole per kg bodyweight (1 ml per 15 kg bodyweight). This dose also delivers 0.097 mg per kg Selenium.

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

The product is very well tolerated at the recommended dose rates. In the case of accidental overdosage, depression and anorexia may occur.

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 period(s)

Meat and offal: 14 days

Milk: 60 hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet Code: QP52AC11

4.2 Pharmacodynamic

Albendazole acts on parasites by interfering with their energy generating metabolism. It inhibits fumarate reductase, which in turn prevents the generation of mitochondrial energy in the form of adenosine triphosphate (ATP). There is other evidence that the mode of action is the prevention of microtubule polymerisation. Differential binding affinities between nematode and mammalian tubulin may explain the selective toxicity of benzimidazoles.

4.3 Pharmacokinetic

In calves, peak plasma levels equivalent to 5.5 micrograms of albendazole and /or metabolites are achieved 15 hours after the administration of an oral dose of 20 mg radio-labelled albendazole per kg bodyweight. Twenty-eight percent of the administered dose is excreted in urine during the first 24 hours, and 47% is excreted over a 9-day period.

Albendazole is metabolised primarily to its sulphoxide and sulphone, which are excreted mostly through the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf-life

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

5.3 Special precautions for storage

Do not store above 25°C.
Protect from light and frost.
Keep container tightly closed.
Shake container well before use.

5.4 Nature and composition of immediate packaging

White HDPE packs with polypropylene screw caps. Packs contain 1 litre (flat bottom backpack), 2.5 litre (backpack) and 5 litre (backpack).

Not all pack sizes may be marketed.

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

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

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

Ancare Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10915/006/001

8. DATE OF FIRST AUTHORISATION

10/01/1997

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

01/10/2026

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).