1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovitec Plus Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Albendazole 150 mg

Excipients:
Selenium (as sodium selenate) 1.5 mg
Potassium sorbate 1.8 mg
Formaldehyde solution 35% 2.0 mg

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
An aqueous, off white, creamy, free-flowing oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Care should be taken to avoid the following practices because they increase the risk of developing 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.

4.5 Special precautions for use

Special precautions for use in animals

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.
Wear suitable protective clothing including impermeable rubber gloves.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

None.

4.8 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.

4.9 Amounts to be administered and administration route

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.

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 infestation: 10 mg albendazole per kg bodyweight (1 ml per 15 kg bodyweight). This dose also delivers 0.097 mg per kg Selenium.

Bodyweight (kg)	Worm Dose (ml)	Worm and Fluke dose (ml)
60	3	4
120	6	8
180	9	12
240	12	16
300	15	20
360	18	24
420	21	28

Worm Dose: Cattle over 420 kg should be given a further 1 ml for each additional 20 kg bodyweight.
Worm and Fluke dose: Cattle over 420 kg should be given a further 1 ml for each additional 15 kg bodyweight.

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

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

4.11 Withdrawal Period(s)

Meat and offal: 14 days
Milk: 60 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazoles and related substances
ATCvet code: QP52AC11

5.1 Pharmacodynamic properties

Albendazole acts on parasites by interfering with their energy generating metabolism. It inhibits fumarase 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 polymerization. Differential binding affinities between nematode and mammalian tubulin may explain the selective toxicity of benzimidazoles.

5.2 Pharmacokinetic properties

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 metabolized primarily to its sulphoxide and sulphone, which are excreted mostly through the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Selenium (as sodium selenate)
Anhydrous citric acid
Colloidal anhydrous silica
Formaldehyde solution 35%
Monopropylene glycol
Macrogol 6000
Polyoxyl sorbate
Potassium sorbate
Xanthan gum
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 below 25°C.
Protect from light and frost.
Keep the container tightly closed.
Shake well before use.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not contaminate ponds, waterways or ditches with the product or used containers.
Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Acravet Limited

8 MARKETING AUTHORISATION NUMBER(S)

VPA10793/003/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/11/1997

10 DATE OF REVISION OF THE TEXT

20/09/2024