

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Osmonds Flexiben 10% SC Oral Suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances:

Albendazole	100.000 mg
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Excipients:

Selenium (as Sodium Selenite)	1.080 mg
Cobalt (as cobalt sulphate)	2.500 mg
Methylparahydroxybenzoate (E218)	2.000 mg
Propylparahydroxybenzoate (E216)	0.200 mg
Green S (E142)	0.018 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

A pale blue-coloured aqueous oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep

4.2 Indications for use, specifying the target species

Osmonds Flexiben SC is a broad spectrum multi-purpose anthelmintic for the control of mature and developing immature forms of gastrointestinal roundworms, lungworms, tapeworms, and adult liver fluke in cattle and sheep. The product is also ovicidal against fluke and roundworms eggs.

In **cattle** it is active against the following species:

Roundworms:

Ostertagia

Haemonchus

Trichostrongylus

Nematodirus

Oesophagostomum

Bunostomum

Cooperia and *Strongyloides* spp.

It is usually effective against inhibited larvae of *Cooperia* and *Ostertagia*.

Lungworms:

Dictyocaulus viviparus

Tapeworms:

Moniezia spp.

Adult liver fluke:

Fasciola hepatica

In **sheep** it is active against benzimidazole susceptible strains of the following species:

Roundworms:

Ostertagia

Haemonchus

Trichostrongylus

Nematodirus (including *N. battus*)

Chabertia and *Oesophagostomum*

It is usually effective against inhibited larvae of *Ostertagia*.

Lungworms:

Dictyocaulus filaria

Tapeworms:

Moniezia spp.

Adult liver fluke:

Fasciola hepatica

Osmonds Flexiben SC is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

4.3 Contraindications

Do not use in sheep producing milk for human consumption.

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

Do not administer other cobalt and selenium supplements concurrently with this product unless specifically advised by your veterinary surgeon.

4.4 Special warnings for each target species

Cattle suffering from severe lung damage due to heavy lungworm infestation may continue to cough for some weeks after treatment.

4.5 Special precautions for use

Special precautions for use in animals

Not to be diluted or mixed with other products.

Avoid the introduction of contamination during use.

The product should only be used in areas where deficiencies of cobalt and selenium are likely to occur. If in any doubt seek the advice of 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 must be taken not to damage the pharyngeal region when dosing, particularly in sheep.

Special Precautions to be taken by the Person Administering the 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)

None known.

4.7 Use during pregnancy, lactation or lay

Do not dose ewes at the 'fluke and worm' dose rate, (7.5 mg/kg), during tupping or for 1 month after removing the rams.

The use of Osmonds Flexiben SC in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.

4.8 Interaction with other medicinal products and other forms of interaction

Administration of ionophores to lambs has been shown to enhance selenium bioavailability. Concurrent administration of ionophores and Osmonds Flexiben S.C may therefore lead to an increased risk of selenium toxicity.

4.9 Amounts to be administered and administration route

For oral administration only using properly calibrated dosing equipment. Estimate bodyweight accurately. One ml of Osmonds Flexiben SC contains 100 mg Albendazole, 1.08 mg elemental selenium and 2.5 mg elemental cobalt. Shake the container before use.

Cattle

Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs.

Dosage: Approximately 7.5 mg albendazole per kg bodyweight.

Fluke and worm dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle.

Dosage: Approximately 10 mg albendazole per kg bodyweight.

Sheep

Worm dose: For the control of roundworms, lungworms, tapeworms, fluke and roundworm eggs.

Dosage: Approximately 5 mg albendazole per kg bodyweight.

Fluke and worm dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in sheep.

Dosage: Approximately 7.5 mg albendazole per kg bodyweight.

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

Not applicable.

4.11 Withdrawal Period(s)

Cattle

Meat: 14 days. Animals intended for human consumption may be slaughtered after 14 days following treatment.

Milk: 60 Hours. Milk intended for human consumption may be taken from animals after 60 hours following treatment

Sheep

Meat: 4 days. Animals intended for human consumption may be slaughtered after 4 days following treatment.

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, Benzimidazoles
ATCvet Code: QP52AC11

5.1 Pharmacodynamic properties

Albendazole belongs to the benzimidazole class of anthelmintics.

Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in the absence of microtubules in the intestinal cells of the nematode, with the result that these cells cannot absorb nutrients, thus causing a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, resulting in the preferential toxicity of albendazole to the helminth and not to the host. Benzimidazoles have also been shown to inhibit the fumarate reductase system of helminths and impair energy production.

The selenium and cobalt are trace elements of use as nutritional supplements and are not intended to be used therapeutically.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Selenium (as Sodium Selenite)
Cobalt (as cobalt sulphate)
Green S (E142)
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Citric Acid Monohydrate
Sodium Citrate
Xanthan Gum
Povidone K90
Polysorbate 20
Propylene Glycol
Simethicone emulsion
Purified Water

6.2 Incompatibilities

Not to be diluted or mixed with other products.

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.

6.5 Nature and composition of immediate packaging

2.5 and 5.0 litre high density polyethylene containers with high density polythene closures and expanded polyethylene liners.

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

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

Cross Vetpharm Group Ltd.
Broomhill Road
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/030/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th June 2007

10 DATE OF REVISION OF THE TEXT

23rd January 2009