Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Keelogane SC 25 mg/ml Oral suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	per	ml
Albendazole	25.00	mg

Excipients	per	ml
Selenium (as sodium selenite)	0.270	mg
Cobalt (as cobalt sulphate)	0.624	mg
Chlorophyll WSI (E141)	3.00	mg
Methyl Parahydroxybenzoate(E218)	2.00	mg
Propyl Parahydroxybenzoate (E216)	0.20	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

Keelogane 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 roundworm eggs.

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*

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*

Keelogane SC is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.
The selenium and cobalt in this product are trace elements of use as nutritional supplements.

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

Care must be taken not to damage the pharyngeal region when dosing particularly in sheep.

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.

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)

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 Keelogane 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 interactions

Administration of ionophores to lambs has been shown to enhance selenium bioavailability. Concurrent administration of ionophores and Keelogane SC 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 Keelogane SC contains 25 mg albendazole, 0.27 mg elemental selenium and 0.624 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

None known.

4.11 Withdrawal period(s)

Cattle
Meat and offal: 14 days.
Milk: 60 hours.

Sheep
Meat and offal: 4 days.
Not permitted for use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimadazoles.
ATCvet code: QP52AC11

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)
Chlorophyll WSI (E141)
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)

Citric acid monohydrate
Sodium Citrate
Xanthum Gum
Povidone K90
Polysorbate 20
Propylene Glycol
Simethicone emulsion
Purified Water

6.2 Major 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: 3 years

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

2.5 litre, 5 litre and 10 litre high density polyethylene containers and high density polyethylene closures with expanded polyethylene liners, containing a pale green suspension.Not all pack sizes may be marketed.

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

Do not contaminate ponds, waterways or ditches with the product or used containers.
Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 June 2003
Date of last renewal: 29 June 2008

10 DATE OF REVISION OF THE TEXT

May 2019