SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovidrench S&C 25 mg/ml Oral Suspension for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Albendazole 25 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl Parahydroxybenzoate	2 mg
Propyl Parahydroxybenzoate	0.2 mg
Copper Chlorophyll Complex Sodium (E141)	3 mg
Cobalt Sulphate Heptahydrate (equivalent to Cobalt)	3 mg (0.624 mg)
Sodium Selenite (equivalent to Selenium)	0.592 mg (0.27 mg)
Citric Acid Monohydrate	
Sodium Citrate	
Xanthan Gum	
Povidone	
Polysorbate 20	
Propylene Glycol	
Simethicone Emulsion	
Water, purified	

A pale green suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle
Sheep

3.2 Indications for use for each target species

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 veterinary medicinal product is also ovicidal against fluke and roundworm eggs.

In cattle it is active against the following species:
Roundworms: *Teladorsagia, Haemonchus, Trichostrongylus, Nematodirus, Oesophagostomum, Bunostomum, Cooperia* and *Strongyloides* spp. It is usually effective against inhibited larvae of *Cooperia* and *Teladorsagia*.
Lungworms: *Dictylcaulus viviparus.*
Tapeworms: *Moniezia* spp.
Adult liver fluke: *Fasciola hepatica.*
The veterinary medicinal product is ovicidal and will kill fluke and roundworm eggs, thus rendering pasture contamination.

In sheep it is active against benzimidazole-susceptible strains of the following species:
Roundworms: *Teladorsagia, Haemonchus, Trichostrongylus, Nematodirus* (including *N. battus*), *Chabertia* and *Oesophagostomum.* It is usually effective against inhibited larvae of *Teladorsagia.*
Lungworms: *Dictyocaulus filaria.*
Tapeworms: *Moniezia* spp.
Adult liver fluke: *Fasciola hepatica.*
The veterinary medicinal product is ovicidal and will kill fluke and roundworm eggs, thus reducing pasture contamination.

3.3 Contraindications

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

3.4 Special warnings

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

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.

Resistance to benzimidazoles has been reported in *Teladorsagia, Haemonchus, Cooperia* and *Trichostrongylus* species in small ruminants. Resistance to albendazole has been reported in *Cooperia* and *Teladorsagia* species in cattle in New Zealand. Therefore the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

To reduce this risk, dosing programmes should be discussed with a veterinary surgeon.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid the introduction of contamination during use.
The veterinary medicinal 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 a veterinary surgeon.
Care should be taken not to damage the pharyngeal region when dosing particularly in sheep.
Do not administer other cobalt and selenium supplements concurrently unless specifically advised by your vet. Not to be diluted.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid direct contact with the veterinary medicinal product.
Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product. In the event of accidental eye exposure, flush eye thoroughly with running water. If irritation persists, seek medical attention. In the event of accidental skin exposure, wash the affected areas with soap and water. If irritation persists, seek medical attention and show the package leaflet or label to the physician. Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

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 its local representative or the national competent authority via the national reporting system. See the label for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The use of the veterinary medicinal product in breeding bulls or pregnant cattle is not expected to interfere with their reproductive performance.
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 veterinary medicinal product can be safely used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
For oral administration only using properly calibrated dosing equipment.
To ensure a correct dose, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
Shake the container before use.
Do not mix with other products.

Cattle:
Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs.
Dosage: 7.5 mg albendazole per kg bodyweight (0.3 ml/kg bodyweight).

Fluke and worm dose: For the additional treatment of adult liver fluke (chronic fascioliasis) in cattle.
Dosage: 10 mg albendazole per kg bodyweight (0.4 ml/kg bodyweight).

Sheep:
Worm dose: For the control of roundworms, lungworms, tapeworms and fluke and roundworm eggs.
Dosage: 5 mg albendazole per kg bodyweight (0.2 ml/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 (0.3 ml/kg bodyweight).

Administration with a suitable drenching gun is recommended.

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

Not applicable.

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 periods

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

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC11

4.2 Pharmacodynamics

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 veterinary medicinal product is also ovicidal against fluke and roundworm eggs.

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. Administration of ionophores to lambs have been shown to enhance selenium bioavailability. Concurrent administration of ionophores and the veterinary medicinal product may therefore lead to an increased risk of selenium toxicity.

Anthelmintic Class: 1-BZ

4.3 Pharmacokinetics

None stated.

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.

5.4 Nature and composition of immediate packaging

1L, 2.5L and 5L high density polyethylene backpacks with high density polyethylene caps (screw fit).

10L high density polyethylene jerricans with high density polyethylene caps (screw fit) with induction reseal liner.

Not all pack sizes may be marketed.

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

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

Do not contaminate ponds, waterways or ditches with the product or used containers.
The veterinary medicinal product should not enter water courses as albendazole may be dangerous for fish and other aquatic organisms.
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

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER

Vm 50146/4033

8. DATE OF FIRST AUTHORISATION

27 November 2001

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

September 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 29 September 2026