

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazole SC

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Mebendazole Ph. Eur.	5 % w/v
Sodium selenite BP(Vet)	0.0875 % w/v
(equivalent to Selenium)	(0.04 % w/v)
Cobalt Sulphate	1.905 % w/v
(equivalent to cobalt)	(0.4 % w/v)

Excipients

Tartrazine (E102)	0.0025 % w/v
Methyl Parahydroxybenzoate Ph. Eur.	0.2 % w/v
Propyl Parahydroxbenzoate Ph. Eur	0.02 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

Chanazole SC is a broad spectrum anthelmintic for the control of roundworms, tapeworms and lungworms in sheep. Mebendazole is ovicidal and is effective against mature and developing immature forms of benzimidazole-susceptible strains of the following parasites:

- Roundworms:** *Ostertagia* spp., *Haemonchus contortus*, *Trichostrongylus* spp., *Cooperia* spp., *Nematodirus* spp., *Strongyloides papillosus*, *Oesophagostomum* spp., *Bunostomum* spp., *Chabertia ovina*. Also useful for the control of *Trichuris ovis*.
- Lungworms:** *Dictyocaulus filaria*.
- Tapeworms:** *Moniezia* spp.

Chanazole SC contains the trace elements selenium and cobalt as an aid in the prevention of selenium and cobalt deficiency.

4.3 Contraindications

As Chanazole SC contains the trace elements selenium and cobalt, other selenium and cobalt supplements must not be used at the same time as Chanazole SC unless specifically advised by your veterinary surgeon.

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

Do not use in sheep producing milk for human consumption.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Chanazole SC must only be used in areas where selenium and cobalt deficiencies are likely to occur, if in any doubt please 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 adviser.

Assess bodyweight as accurately as possible before calculating the dosage.

Care must be taken to avoid injury to the pharyngeal region with the nozzle of a dosing gun.

Special Precautions to be taken by the Person Administering the Product to Animals

Direct contact with 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

Chanazole SC can be safely used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Administered as an oral drench using suitable drenching equipment.

The dose rate for sheep is 15.0 mg/kg mebendazole, 0.12 mg/kg selenium and 1.2 mg/kg cobalt which is equivalent to 3 ml Chanazole SC per 10 kg bodyweight.

Dose:

Lambs up to 10 kg	3.0 ml
11 - 20 kg	6.0 ml
21 - 30 kg	9.0 ml
31 - 40 kg	12.0 ml
Sheep 41 - 50 kg	15.0 ml
51 - 60 kg	18.0 ml
61 - 70 kg	21.0 ml
71 - 80 kg	24.0 ml
81 - 90 kg	27.0 ml
91 - 100 kg	30.0 ml

Shake container well before use.

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

Not applicable

4.11 Withdrawal Period(s)

Not for use in sheep producing milk for human consumption. Animals must not be slaughtered for human consumption during treatment. Sheep may be slaughtered for human consumption only after 14 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Mebendazole, a potent benzimidazole anthelmintic agent, destroys the intestinal absorptive capacity of the parasite by disrupting microtubule formation.

Mebendazole is poorly absorbed, with more than 90% of the orally administered dose passing through the intestine as unchanged mebendazole. Selenium and Cobalt are readily absorbed following oral administration.

Mebendazole belongs to the Benzimidazoles (1-BZ) class of anthelmintics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartrazine (E102)
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Citric Acid Monohydrate
Sodium Citrate
Propylene Glycol
Polysorbate 20
Povidone (90F)
Xanthan Gum
Simethicone emulsion
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf-life

24 months

6.4 Special precautions for storage

Do not store above 25°C. Protect from frost.

UK only: Keep out of the reach of children.

6.5 Nature and composition of immediate packaging

An orange-peach coloured suspension contained in:

- i) High density polythene flexi pack or rigid pack
- ii) Closure:
 - a. Aluminium foil seal with a polypropylene screw cap (2.5 L and 5 L)
 - b. Polypropylene screw cap only (1 L)

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 and containers should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd
7 Rodney Street
Liverpool L19 HZ
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10879/1/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd January 2000