

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec Super 10 mg/ml / 100 mg/ml Solution for Injection for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:	Ivermectin	10mg
	Clorsulon	100mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol Formal
Propylene Glycol
Monoethanolamine

A clear colourless to pale yellow coloured non-aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

For the treatment of mixed infestation of adult liver fluke and gastro-intestinal roundworms, lungworms, eye worms, and/or mites and lice of beef and non-lactating dairy cattle.

Gastrointestinal Roundworms (adult and fourth-stage larvae):

Ostertagia ostertagi (including inhibited larval stages)

O. lyrata

Haemonchus placei

Trichostrongylus axei

T. colubriformis

Cooperia oncophora

C. punctata

C. pectinata

Bunostomum phlebotomum

Oesophagostomum radiatum

Strongyloides papillosus (adult)

Nematodirus helvetianus (adult)

Nematodirus spathiger (adult)

Trichuris spp. (adult)

Lungworm (adult and fourth-stage larvae):

Dictyocaulus viviparus

Liver Fluke (adult):

Fasciola hepatica

Eye Worms (adult):

Thelazia spp.

Warbles (parasitic stages):

Hypoderma bovis

H. lineatum

Mange mites:

Psoroptes bovis

Sarcoptes scabiei var. *bovis*

Sucking Lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

The veterinary medicinal product may also be used as an aid in the treatment of biting lice (*Damalinia bovis*) and the mange mite *Chorioptes bovis*, but complete elimination may not occur.

Persistent Activity

The veterinary medicinal product given at the recommended dosage of 1 ml/50 kg bodyweight controls re-infection with *Haemonchus placei*, *Cooperia* spp. and *Trichostrongylus axei*, acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

3.3 Contraindications

Do not use this veterinary medicinal product intravenously or intramuscularly. This veterinary medicinal product is a low volume veterinary medicinal product authorised for use in cattle. It must not be used in other species as severe adverse reactions, including fatalities in dogs, may occur, especially Collies, Old English Sheepdogs and related breeds or crosses. Do not use in cases of hypersensitivity to the active ingredient or to any of the excipients.

3.4 Special warnings

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 bodyweight, misadministration of the veterinary medicinal 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 macrocyclic lactones (which includes ivermectin) has been reported in *Ostertagia ostertagi* and *Cooperia* spp. in cattle within the EU. 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal product does not contain any antimicrobial preservative. Swab septum before removing each dose. To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer the veterinary medicinal product at the end of the period of fly activity and before the larvae reach their resting sites: seek professional advice on the correct timing of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Do not eat, drink or smoke whilst handling the veterinary medicinal product.

Wash hands after use.

Direct contact with the skin should be avoided.

Personal protective equipment consisting of gloves and glasses should be worn when handling the veterinary medicinal product.

Take care to avoid self-injection: the veterinary medicinal product may cause local irritation and/or pain at the site of injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

The veterinary medicinal product is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore repeated treatment of animals on a pasture with an ivermectin-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

3.6 Adverse events

Cattles:

Undetermined frequency (cannot be estimated from the available data):	injection site pain ¹ Injection site swelling. ²
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¹Transitory discomfort

²Soft-tissue reaction, resolve over time without treatment

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

Lactation:

Can be used during lactation.

Can be used in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Dosage and duration of treatment

For subcutaneous use.

A single dose of 1ml of the veterinary medicinal product per 50kg bodyweight, i.e. 200µg ivermectin and 2mg clorsulon per kg bodyweight.

Method of administration

The veterinary medicinal product should be administered only by subcutaneous injection under the loose skin in front of or behind the shoulder.

Divide doses greater than 10ml between two injection sites. A sterile 17 gauge (15-20 mm) needle is recommended.

Different injection sites should be used for other parenteral veterinary medicinal products administered concurrently. When using the 500 ml pack size use only automatic syringe equipment. For the 50 ml pack size, use of a multidose syringe is recommended.

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person.

To ensure a correct dosage, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

If animals are to be treated collectively rather than individually, to avoid under- or over-dosing, they should be grouped according to their bodyweight and dosed accordingly.

When the temperature of the veterinary medicinal product is below 5°C, difficulty in administration may be encountered due to increased viscosity. Warming the veterinary medicinal product and injection equipment to about 15°C will greatly increase the ease with which the veterinary medicinal product can be injected.

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

A dose of 25 ml per 50kg bodyweight (25 times the recommended dose level) may result in injection site lesions, including tissue necrosis, oedema, fibrosis and inflammation.

No other drug-related reactions have been observed.

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

Meat and offal: 66 days

Milk: Do not use in cattle producing milk for human consumption.

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA51

4.2 Pharmacodynamics

Ivermectin is a member of the macrocyclic lactone class of endectocides, which have a unique mode of action. It has broad and potent antiparasitic activity. It binds selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand gated chloride channels and they do not readily cross the blood-brain barrier.

Clorsulon is a sulphonamide and is rapidly absorbed in the blood stream. It is bound to the erythrocytes and plasma which are ingested by the fluke. Clorsulon inhibits the glycolytic enzymes in the fluke and deprives it of its main source of metabolic energy.

4.3 Pharmacokinetics

After subcutaneous administration of the veterinary medicinal product at the recommended dose, 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight, the plasma profile demonstrated a slow absorption of ivermectin with mean maximum plasma levels of 65.8 ng/ml reached at 36 hours. In contrast, clorsulon appeared rapidly absorbed with mean maximum plasma levels of 2.58 µg/ml reached at 6 hours.

The terminal half-life for the two active ingredients were determined as follows:

Ivermectin approximately 3.79 days and Clorsulon approximately 3.58days

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibilities studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years Shelf-life after first opening the immediate packaging: Following withdrawal of the first dose, use the veterinary medicinal product within 28 days. Discard unused material.

5.3 Special precautions for storage

Protect from light.

Keep the container in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Container material: High density polyethylene

Container closure: Siliconised grey bromobutyl rubber stopper

Container colour: Natural

Carton containing individual bottles of 50, 250 or 500 ml'

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.

The veterinary medicinal product should not enter water courses as this veterinary medicinal product is dangerous for fish and other aquatic organisms.
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.

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

Chanelle Pharmaceuticals Manufacturing Ltd

7. MARKETING AUTHORISATION NUMBER

Vm08749/5061
Vm 08749/3024

8. DATE OF FIRST AUTHORISATION

16 April 2010

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

July 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: 05 August 2026