SUMMARY OF THE 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

Active substances:

1 ml of solution contains:
Ivermectin 10mg
Clorsulon 100mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the 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 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 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.

4.3 Contraindications

Do not use this product intravenously or intramuscularly. This product is a low volume 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 animals with a known sensitivity to the active ingredient or to any of the excipients.

4.4 Special warnings for each target species

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 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 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.

4.5 Special precautions for use

i) Special precautions for use in animals

This 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 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.

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

Do not eat, drink or smoke whilst handling the product.
Wash hands after use.
Direct contact with the skin should be avoided.
Wear gloves and glasses when handling the veterinary medicinal product.
Take care to avoid self-injection: the product may cause local irritation and/or pain at the site of injection.
In case of accidental self injection, seek medical advice and show the label to the doctor.

iii) Other precautions

The 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.

4.6 Adverse reactions (frequency and seriousness)

Transient discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the site of injection has been observed. These reactions disappeared without treatment.

4.7 Use during pregnancy, lactation or lay

Can be used in pregnancy and lactation.

Can be used in breeding animals.
See section 4.11.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dosage and duration of treatment

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

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

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

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.

4.11 Withdrawal period(s)

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Endectocides
ATC Vet Code: QP54AA51

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

After subcutaneous administration of the 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

5.2 Environmental properties

Like other macrocyclic lactones, Ivermectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of Ivermectin may take place over a period of several weeks. Faeces containing Ivermectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Formal
Propylene Glycol
Monoethanolamine

6.2 Incompatibilities

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

6.3 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 product within 28 days. Discard unused material.

6.4 Special Precautions for storage

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

6.5 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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
Do not contaminate surface waters or ditches with product or used container.

7. MARKETING AUTHORISATION HOLDER

Chanelle Animal Health
7 Rodney Street
Liverpool
L1 9HZ
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 11990/4054

9. DATE OF FIRST AUTHORISATION

16 April 2010

10. DATE OF REVISION OF THE TEXT

13 March 2020

Approved 13 March 2020