Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec Super Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance(s):

Ivermectin 10 mg
Clorsulon 100 mg

Excipients**:**
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 and control of the following parasites:

Gastrointestinal Roundworms (adult and fourth-stage larvae):
Ostertagia spp. (including inhibited *O. ostertagi*)
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia spp.
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult only)
Nematodirus helvetianus (adult only)
Nematodirus spathiger (adult only)
Toxocara vitulorum
Trichuris spp. (adult only)

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 eursternus
Solenopotes capillatus `

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

Persistent Activity
When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with the product at the recommended dose rate can control re-infection with *Haemonchus placei* and *Cooperia* spp., acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocalus viviparus* acquired up to 28 days after treatment.

4.3 Contraindications

This product is not to be used intramuscularly or intravenously. This product is registered for use in cattle only. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.
Do not use in animals with known hypersensitivity to the active ingredient or 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 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.

4.5 Special precautions for use

Special precautions for use in animals

Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing. Veterinary advice should also be sought if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance might be involved.

Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or crosses, and also in turtles/tortoises.
Divide doses in excess of 10 ml between different injection sites and use different sites to those used for other parenteral medications.
Swab septum before removing each dose. Avoid the introduction of contamination during use.
When using the 250 ml and 500 ml pack sizes, use only automatic syringe equipment. For the 50 ml pack size, the use of a multidose syringe is recommended.

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

Do not eat, drink or smoke while handling the product.
Wash hands after use.
Take care to avoid self-administration; the product may cause local irritation and/or pain at the site of injection.
In the event of accidental skin contact, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water.

4.6 Adverse reactions (frequency and seriousness)

Transitory discomfort has been observed in some cattle following subcutaneous administration. Soft tissue swellings may occur at the site of injection. These reactions resolve over time without treatment.

4.7 Use during pregnancy, lactation or lay

The product is safe for use at any stage of pregnancy or lactation. However, the product is not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.
The product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions have been identified with other products.

4.9 Amounts to be administered and administration route

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. The accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.
The product should be given only by subcutaneous injection at the recommended dosage level of 1 ml/50 kg bodyweight (based on a dosage level of 200 mcg ivermectin plus 2 mg clorsulon per kg bodyweight) under the loose skin in front of, or behind, the shoulder. Divide doses greater than 10 ml between two injection sites. A sterile 17 gauge ½-inch (15-20 mm) needle is recommended. When the temperature of the product is below 5ºC, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15ºC will greatly increase the ease with which the product can be injected. Different injection sites should be used for other parenteral products.

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

The administration of 5 ml per 50 kg bodyweight (5 x the recommended dose rate.) resulted in injection site lesions (including swelling, sensitivity, oedema and inflammation).
No other drug-related adverse reactions are expected.

4.11 Withdrawal Period(s)

Meat and offal: 66 days.
Not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QP54AA51

Pharmacotherapeutic Group: Endectocides, ivermectin combinations.

5.1 Pharmacodynamic properties

Ivermectin
Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind 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
Clorsulon is rapidly absorbed into the circulating blood. Erythrocytes with bound drug as well as plasma are ingested by *Fasciola* spp. Adult *Fasciola* spp. are killed by clorsulon because of inhibition of enzymes in the glycolytic pathway, which is their primary source of energy.

5.2 Pharmacokinetic properties

Maximum plasma concentration
After subcutaneous administration of 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight, maximum plasma concentrations of ivermectin (Cmax: 65.80 ng/ml) were achieved 1-2 days after treatment and maximum plasma concentrations of clorsulon (Cmax: 2.58 µg/ml) were achieved approximately 8 hours after treatment

Excretion: length of time and route
A dose rate of 2 mg clorsulon and 0.2 mg ivermectin per kg bodyweight was administered by subcutaneous injection. For ivermectin, liver had the highest average residues, peaking on day 7 post dose at an average of 220 ppb. Depletion followed so that by days 28 and 35 the liver residues were 11 and 6 ppb respectively. Fat residues also peaked on day 7 at an average of 160 ppb. They decreased to 6 and 4 ppb by days 28 and 35 respectively. Muscle and kidney residues were negligible at 1 and 2 ppb respectively by day 28.

For clorsulon, kidney had the highest average residues of 0.54 ppm (540ppb) on day 3 post dose. At the same time, liver averaged 0.20 ppm, muscle averaged 0.06 ppm and fat averaged 0.02 ppm. Rapid depletion followed, resulting in average residues at or below the detection limit of 0.01 ppm by day 21 for all tissues.

In cattle receiving a single dose of tritium-labelled ivermectin (0.2-0.3 mg/kg bodyweight), analyses showed that composites of faeces collected during the first 7 days after dosing contained almost all the dosed radioactivity, only about 1-2% being excreted in the urine. Analyses of the faeces showed that about 40-50% of the excreted radioactivity was present as unaltered drug. The remaining 50-60% was present as metabolites or degradation products.

During the first 7 days following intra-ruminal administration of 7 mg/kg clorsulon to a 270 kg steer, about 90% of the radiolabel in the administered dose was found in the urine (25%) and the faeces (65%).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Formal
Propylene Glycol
Ethanolamine (for pH adjustment)

6.2 Incompatibilities

In the absence of compatibility 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: 28 days

6.4 Special precautions for storage

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 volume: 50, 250 or 500 ml
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
County Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/068/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th June 2010

Date of last renewal: 24th June 2015

10 DATE OF REVISION OF THE TEXT