Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec 5 mg/ml Pour-on Solution for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Ivermectin 5 mg/ml

Excipients
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Pour-on solution.
A clear, slightly yellow coloured solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the effective treatment and control of the following species of gastrointestinal roundworms, lungworms, warbles, mites and lice:

Gastro-intestinal roundworms (adults and fourth stage larvae)
Ostertagia ostertagi (including inhibited *O. ostertagi*)
Haemonchus placei
Trichostongylus axei
Trichostrongyulus colubiformis
Cooperia spp
Oesophagostomum radiatum

Strongyloides papillosus (adult)
Trichuris spp (adult)

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eye Worms (adult)

Thelazia spp

Warbles (parasitic stages):
Hypoderma bovis
Hypoderma lineatum

Mites:
Chorioptes bovis
Sarcoptes scabiei var. *bovis.*

Sucking lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

Biting lice
Damalinia bovis

Animec Pour-On given at the recommended dosage of 500 micrograms/kg bodyweight, controls infections with *Trichostrongylus axei* and *Cooperia* acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment and *Dictyocaulus viviparus* (lungworm) acquired during the first 28 days after treatment.
It also controls horn flies (*Haematobia irritans*) for up 35 days after treatment.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient. This product is for application to skin surface only, do not give orally or parenterally.

4.4 Special warnings for each target species

Cattle should not be treated when hair or hide is wet. Rain falling on cattle in less than two hours after dosing may result in reduced efficacy. However, the efficacy of the product against established infections of *O. ostertagi* or *D.viviparus* is not adversely affected if the hide is wet or if rain falls shortly after treatment. Do not apply to areas of skin that may have mange scabs or other lesions or to areas contaminated with mud or manure.

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.
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

Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.
Frequent and repeated use may lead to the development of resistance.

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

The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons.
Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. Use only in well-ventilated areas or outdoors.
As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and seek medical attention. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

The product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended 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 interactions

The product may be used concurrently with foot and mouth disease vaccine or clostridial vaccine.

4.9 Amounts to be administered and administration route

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dose of 500 micrograms/kg bodyweight)
Administration: The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.
The product should be used with appropriate dosing equipment.
To ensure administration of correct dose, body weight 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, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

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

No sign of toxicity appeared up to 1.5 mg/kg (3 times the recommended dose rate).
No antidote has been identified.

4.11 Withdrawal period(s)

Meat and offal: 28 days.
Milk: Not permitted for use in lactating animals producing milk for human consumption. Do not use in lactating dairy cows including pregnant heifers within 60 days prior to calving.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antiparasitic Products, insecticides and repellents, Endectocides.
ATCvet code: QP54AA01.
Ivermectin is a member of the avermectin group.

5.1 Pharmacodynamic properties

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 hyperpolarisation 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.

5.2 Pharmacokinetic particulars

After topical administration of the product at the recommended dose of 500 microgram per kg bodyweight, the plasma concentrations increased to an average plateau of 12-16 ng/ml between 36-144 hours post treatment (Tmax is 3.7 days) with a Cmax of 16.89 ng/ml. After day 6 the ivermectin levels gradually decreased to an average of less than 2 ng/ml at 28 days. The concentrations mentioned relate to the main component of ivermectin, 22,23-dihydroaverectin B1a. The AUC for ivermectin is 4175 ng/ml/hr with a distribution half life of 7.2 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crodamol Cap
Trolamine
Isopropyl alcohol

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Flammable - keep away from heat, sparks, open flames or other sources of ignition. Close container when not in use. Bottles should remain upright during storage.

6.5 Nature and composition of immediate packaging

High density polyethylene container (flat bottomed flexi packs) with a 38mm tamper evident closure (1 L, 2.5 L and 5 L). The 1 L container has a dial a dose dosing cup.
Pack sizes: 1 L, 2.5 L, 5 L and 6 L.
The 6 L pack consists of a 5 L and 1 L pack combined in one carton.

High density polyethylene squeeze-measure-pour containers with child resistant closures (250 ml, 500 ml and 1 L).

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements. Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. The product should not enter watercourses as this may be dangerous to fish and other aquatic organisms. Do not contaminate lakes or streams with unused product or waste material as free ivermectin may adversely affect fish or certain water borne organisms.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/152/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 December 2004
Date of last renewal: 02 December 2009

10 DATE OF REVISION OF THE TEXT

November 2018