Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec 1 % Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Ivermectin 1% w/v (10 mg/ml)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Pigs

4.2 Indications for use, specifying the target species

Animec Injection is indicated for the effective treatment and control of the following harmful parasites of cattle and pigs:

Cattle:
Gastro-intestinal 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),
Nematodirus helvetianus (adult),
N. spathiger (adult),
Toxocara vitulorum,
Trichuris spp. (adult).

Lungworms (adult and fourth stage larvae):

Dictyocaulus viviparus.

Eye worms (adult):
Thelazia spp.

Warbles (parasitic stages):
Hypoderma bovis and *H. lineatum*.

Mange mites:
Psoroptes bovis,
Sarcoptes scabiei var. *bovis*.

Sucking lice:
Linognathus vituli,
Haematopinus eurysternus
Solenopotes capillatus.

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

Persistant activity:
Treatment at the recommended dose rate controls 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 *Dictyocaulusviviparus* acquired up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of Animec injection for grazing animals it is recommended that calves which are set-stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season, provided they are set-stocked, all the calves are included in the programme and that no untreated cattle are added to the pasture.
Treated calves should always be monitored according to good husbandry practices.

Pigs:
Gastrointestinal worms (adult and fourth stage larvae):
Ascaris suum,
Hyostrongylus rubidus,
Oesophagostomum spp,
Strongyloides ransomi (adult and somatic larval stage)

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var.suis

4.3 Contraindications

Do not use in case of known hypersensitivity to the active ingredient.
Animec Injection for Cattle and Pigs has been formulated specifically for use in those species. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

Do not administer by the intravenous or intramuscular route.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid under dosing animals should be grouped according to their body weight and dosed according to the heaviest animal in the group.

Special Precautions to be taken by the Person Administering the Product to Animals
Take care to avoid self administration; the product may cause local irritation and/or pain at the site of injection.

4.6 Adverse reactions (frequency and seriousness)

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

Pigs:
Mild and transient pain reactions may be seen in some pigs following subcutaneous injection. All these reactions disappeared without treatment.

4.7 Use during pregnancy, lactation or lay

Animec Injection for cattle and pigs can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. It can be used in breeding sows and boars and will not affect fertility. Animec Injection for cattle and pigs can be given to all ages of animals including young calves and piglets. Please refer to point 4.11.

4.8 Interaction with other medicinal products and other forms of interactions

Animec Injection can be used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.

4.9 Amounts to be administered and administration route

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle, and 33 kg of bodyweight of pigs. The injection may be given with any standard automatic on single-dose or hypodermic syringe. Use of 17 gauge x ½ inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended. If using a single dose hypodermic syringe, use a separate sterile needle to withdraw Animec Injection from the container.

Cattle:
Animec Injection should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle. This is equivalent to 1 ml per 50 kg bodyweight.

Pigs:
In pigs, the recommended dosage level is 300 mcg ivermectin per kg bodyweight. This is equivalent to 1 ml per 33 kg bodyweight. The recommended route of administration is by subcutaneous injection into the neck.

Young Pigs:
In young pigs, especially those below 16 kg for which less than 0.5 ml Animec Injection is indicated, dosing accurately is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

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

Cattle:
Single dose of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.

Pigs:
A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.

4.11 Withdrawal period(s)

Cattle:
Must not be treated within 49 days of slaughter for human consumption.
Not permitted for use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

Pigs:
Must not be treated within 28 days of slaughter for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocide
ATC vet code: QP54AA01

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 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 (GABA).
The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gates 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

Maximum plasma concentration:

Cattle:
At a dose level of 0.2 mg ivermectin per kg a maximum plasma concentration of 35-50 ng/ml is reached in ±2 days and the half-life in plasma is of 2.8 days.

It is also established that ivermectin is carried mainly in the plasma (80%). This distribution between plasma and blood cell remains relatively constant.

Pig:
During trials carried out at a dose level of 0.3 mg ivermectin per kg bodyweight, peak plasma concentrations were reached in 3 (±0.5) days and the drug persisted in plasma for up to 28 days.

Excretion: length of time and route

Cattle:
Only about 1 - 2% is excreted in the urine the remainder is excreted in the faeces, approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products.

Pigs:
Biliary excretion is also the major route of ivermectin excretion in pigs.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol Glycerin formal

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.Following withdrawal of the first dose, use the product within 28 days.

6.4 Special precautions for storage

None.

6.5 Nature and composition of immediate packaging

Multidose polyethylene bottles of 50 ml, 250 ml and 500 ml sealed with bromobutyl seals and aluminium overseals.

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

Extremely dangerous to fish and aquatic life. Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/147/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 January 2001
Date of last renewal: 10 January 2006

10 DATE OF REVISION OF THE TEXT

November 2018