SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Animec 10 mg/ml solution for injection for Cattle and Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Ivermectin 10 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear colourless to slight yellow-coloured solution with no visible particulates.

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle (beef and non-lactating dairy cattle) and Pigs.

4.2 Indications for use, specifying the target species

Treatment of infections with the following parasites in beef and non-lactating dairy cattle or pigs:

Cattle:
Gastro-intestinal roundworms (adult and fourth stage larvae):
Ostertagia spp. (including inhibited *O.ostertagi)*
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia spp.
Oesophagostomum radiatum
*Nematodirus helvetianus (*adult*)*
N. spathiger (adult)
Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus.
Warbles:
Hypoderma bovis
H. lineatum.

Mange mites:
Psoroptes bovis

Sarcoptes scabiei var*. bovis.*

Sucking lice:
Linognathus vituli
Haematopinus eurysternus

Pigs:
Gastrointestinal roundworms: (adult and fourth stage larvae):
Ascaris suum
Hyostrongylus rubidus
Oesophagostomum spp.
Strongyloides ransomi (adult only)

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var*. suis*

The use of the product in cattle should take into account geographical differences in the occurrence patterns of parasites.

4.3 Contraindications

Do not administer by the intravenous or intramuscular route.
Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in dogs or cats as severe adverse reactions may occur (see also section 4.5).

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.

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 ivermectin has been reported in *Cooperia spp.* and in *Ostertagia ostertagi* in cattle. Resistance has also been reported in *Haemonchus contortus* in cattle outside the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals
In cattle, to avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.

Avermectins may not be well tolerated in non-target species. Cases of intolerance with fatal results are reported in dogs – especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises. In addition, care should be taken to avoid ingestion of spilled product or access to used containers by these other species.

Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The product may cause local irritation and/or pain at the site of injection. Direct contact of the product with the skin should be avoided. Take care to avoid self administration.
Do not smoke or eat while handling the product.
Wash hands after use. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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 repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

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

The product can be administered during pregnancy and lactation in cows (see section 4.11 for details relating to the use in dairy cattle) and sows. It can be used in breeding sows and boars and will not affect fertility.

4.8 Interaction with other medicinal products and other forms of interaction

Do not combine with vaccination against lungworm. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

4.9 Amounts to be administered and administration route

For single administration only by subcutaneous injection. Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle, and 33 kg of bodyweight of pigs. Replace with a fresh sterile needle after every 10 to 12 animals. Massage the injection site after administration of the product. Injection of wet or dirty animals is not recommended.

To ensure administration of a 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 over-dosing.

Cattle:
The product should be given only by subcutaneous injection at the recommended dosage level of 200 µg 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.
The volume administered per injection site should not exceed 10 ml.

Pigs:
In pigs, the recommended dosage level is 300 µg 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 that 0.5 ml of the product 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

In the case of overdose a symptomatic treatment should be given.

Cattle
Single doses 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
Meat and offal: 49 days.
Do not use in lactating cows producing milk for human consumption. Do not use in cattle producing milk for human consumption or in dairy cows within 60 days prior to calving.

Pigs
Meat and offal: 28 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Endectocides
ATCvet 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 this 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.

5.2 Pharmacokinetic properties

Cattle
Maximum plasma concentration
At a dose level of 200 µg ivermectin per kg a maximum plasma concentration of 35-50 ng/ml is reached in ± 2 days.
It is also established that ivermectin is carried mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.

Excretion: length of time and route
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.

Pig
Maximum plasma concentration
During trials carried out at a dose level of 300 µg ivermectin per kg bodyweight, peak plasma concentrations were reached in 3 (±0.5) days.

Excretion: length of time and route
Biliary excretion is also the major route of ivermectin excretion in pigs.

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
Glycerol Formal

6.2 Major Incompatibilities

In the absence of incompatibility 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

This veterinary medicinal product does not require any special storage precautions.

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.
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 veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
The product should not enter water courses as this may be dangerous to fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd.
7 Rodney Street
Liverpool
L1 9HZ

8. MARKETING AUTHORISATION NUMBER

Vm 11990/4023

9. DATE OF THE FIRST AUTHORISATION

21 September 2000

10. DATE OF REVISION OF THE TEXT

June 2018

Approved: 15 June 2018