

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Genesis 1% Pour-on Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Abamectin 1 % w/v

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Pour on solution

Clear straw-coloured oily liquid

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (Beef and non-lactating dairy cattle).

4.2 Indications for use, specifying the target species

A broad spectrum endectocide of the avermectin family, effective against internal and external parasites sensitive to this family. For the treatment and control of the following mature and immature roundworms in cattle:

Haemonchus spp.

Ostertagia spp.

Cooperia spp.

Trichostrongylus spp.

Oesophagostomum spp.

Nematodirus spp.

Trichuris spp. (adults only)

Dictyocaulus spp.

Also for the treatment and control of sucking and biting lice (*Linognathus vituli* and *Damalinia bovis*).

4.3 Contraindications

Do not concurrently treat animals with drugs which can increase GABA activity such as barbitol.

Do not treat animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Assess bodyweight as accurately as possible before calculating dosage.

Intensive use or misuse of anthelmintics may give rise to drug resistance. To reduce this risk, dosing programs should be discussed with your veterinary surgeon.

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

Avoid contact with the skin.

The use of plastic gloves is advised.

Do not smoke or eat while handling the product.

Wash hands after use.

Do not use in other species.

If the drug is taken by mistake immediately seek medical treatment. Emetine or ephedrine may be useful.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Do not use in cattle producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Shake well before use.

Genesis Pour-on is ready to use through standard pour-on equipment.

Cattle:

1ml/20kg bodyweight (based on the recommended dose of 500 micrograms of abamectin per kg bodyweight) poured on the mid-back of the animal. Using the 200 ml and 400 ml pump packs, 1 stroke per 44 kg bodyweight.

Rain Resistance

Clinical trials have shown that the efficacy of Genesis Pour-on is not affected by simulated rainfall 1 hour after treatment based on faecal egg counts 3 weeks after treatment. It is advised not to treat cattle when the hide or hair is wet.

Dosing regime

To obtain maximum benefit from the persistent activity of Genesis Pour-On, calves which are set-stocked in their first grazing season should be treated at turn out and at 8 weeks intervals.

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

Ancare trials showed that a dose of 1000 microgram/kg single or repeated after 21 days caused no adverse drug reactions, however several fold overdose of the injectable formulation of Ancare (Genesis Injection) can cause toxicity; animals will become recumbent within 24 hours and may not recover; there is no antidote.

4.11 Withdrawal period(s)

Cattle must not be treated within 35 days of slaughter for human consumption.

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 or IMMUNOLOGICAL PROPERTIES

Active Ingredients

Abamectin or Avermectin B₁ is the natural fermentation product from *Streptomyces avermitilis* containing not less than 90% of the B_{1a} component and not more than 10% of the B_{1b} component.

5.1 Pharmacodynamic properties

The action of avermectins is on nematode and arthropod parasites by paralysing them through potentiating the presynaptic release of gamma amino butyric acid (GABA).

5.2 Pharmacokinetic particulars

The pharmacokinetic profile of avermectins can be influenced by the formulation used. Genesis Pour-on is formulated in a carrier vegetable oil base. Vegetable oils are preferred to effectively cause permeation through the skin. This was reflected by the persistent (35 days) blood levels of abamectin.

Avermectins are widely dispersed in all tissues with the liver and fat levels being the highest. Excretion is mainly intra intestinal, through bile, and the drug is eliminated via the faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Soya bean oil

6.2 Major incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 9 months

6.4 Special precautions for storage

Store below 25°C
Protect from light

6.5 Nature and composition of immediate packaging

1 L and 2.5 L back pack flat bottomed HDPE containers provided with a cap on which normal pour-on equipment can be fitted.

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

Abamectin is extremely dangerous to fish and aquatic life. Drug containers and any residual contents should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Ancare Ireland Ltd.
30 Coolmine Business Park
Clonsilla Road
Dublin 15
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10915/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th December 2000

Date of last renewal: 20th December 2005

10 DATE OF REVISION OF THE TEXT

July 2018