

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Abacare 1% w/v Pour-On Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active:

Abamectin 1% w/v

Excipients:

Benzyl Alcohol 20% w/v (as preservative)

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Pour-on Solution.

A clear straw coloured oily solution.

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 the 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* adults and *Dictyocaulus* spp. Also for the treatment and control of sucking and biting lice (*Linognathus vituli* and *Damalinia bovis*, respectively).

4.3 Contraindications

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

Do not use in known cases of hypersensitivity to the active ingredient.

Do not use in other species.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Assess body weight 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 Product to Animals

Avoid contact with the skin.

Do not smoke or eat while handling the product.

The use of plastic gloves is advised.

Wash hands after use.

If the drug is taken by mistake immediately seek medical treatment.

Emetine or Ephredine 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

Abacare Pour-on is ready to use through standard pour-on equipment. It is Good Veterinary/Farming Practice to calibrate administration equipment. Cattle: 1ml /20 kg body weight (based on recommended dose of 500 micrograms of Abamectin per kg body weight) poured on the mid-back of the animal if using the pump pack or using a pour-on gun attached to the specially made container cap.

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

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 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 cows 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

Abamectin or Avermectin B1 is the natural fermentation product from *Streptomyces avermitilis* containing not less than 90% of the B1a component and not more than 10% of the B1b component.

ATC Vetcode: QP54AA02

5.1 Pharmacodynamic properties

The action of the 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 may be influenced by the formulation used. Abacare Pour-on is formulated in a carrier vegetable oil base. Vegetable oils are preferred to effectively cause permeation through the skin. The persistent (35 days) blood levels of Abamectin reflected this. 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

Do not store above 25°C.

Protect from light.

Store in tightly closed original container in the upright position.

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. Do not contaminate surface waters or ditches with the product or used containers. 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

J. & M. Veterinary Services Ltd
30 Coolmine Business Park,
Clonsilla Road
Dublin 15
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10954/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd February 2001
Date of last renewal: 22nd February 2006

10 DATE OF REVISION OF THE TEXT

July 2018