1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Abacare 10 mg/ml Pour-On Solution for Cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Abamectin 10 mg/ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol	250 mg/ml
Soya Bean Oil	

Pour-on Solution.
A clear straw coloured oily solution.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle (Beef and non-lactating dairy cattle).

3.2 Indications for use, for each 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).

3.3 Contraindications

Do not concurrently treat animal with drugs which can increase GABA activity, such as barbital.
Do not use in cases of hypersensitivity to the active ingredient. Do not use in other species.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species

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 veterinary medicinal product to animals

Avoid contact with the skin. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician. Emetine or Ephredine may be useful.

Personal protective equipment consisting of plastic gloves should be worn when handling the veterinary medicinal product. Do not smoke or eat while handling the veterinary medicinal product. Wash hands after use.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy. See also SPC section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Pour-on use.
The veterinary medicinal product 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

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.

4. PHARMACOLOGICAL or IMMUNOLOGICAL INFORMATION

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.

4.1 ATCvet code: QP54AA02

4.2 Pharmacodynamics

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).

4.3 Pharmacokinetic

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.

5 PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months

5.3 Special precautions for storage

Do not store above 25˚C. Protect from light.

Store in tightly closed original container in the upright position.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ABAMECTIN IS EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used containers.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6 NAME OF THE MARKETING AUTHORISATION HOLDER

Acravet Limited

7 MARKETING AUTHORISATION NUMBER(S)

VPA10793/004/001

8 DATE OF FIRST AUTHORISATION

23/02/2001

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

12/08/2026

10 CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).