

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Qualimec Cattle Pour-on

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml Pour-on solution contains:

Active substance(s):

Ivermectin 5 mg

Excipient(s):

Benzyl alcohol (E1519) 10 mg

N-methylpyrrolidone 35.5 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pour-on solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

In cattle: For the treatment of infections with the following parasites:

Gastro-intestinal worms (adult and fourth stage larvae):

Haemonchus placei, *Ostertagia ostertagi* (including inhibited larvae), *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia spp.*, *Strongyloides papillosus* (adult), *Oesophagostomum radiatum*, *Trichuris spp.* (adult)

Lungworm (adult and fourth stage larvae):

Dictyocaulus viviparus

Eye worms (adults):

Thelazia spp.

Warbles (parasitic stages):

Hypoderma bovis and *H. lineatum*.

Mange mites:

Sarcoptes scabiei var. bovis and *Chorioptes bovis*

Sucking lice:

Linognathus vituli and *Haematopinus eurysternus*.

Biting louse:

Damalinia bovis

Given at the dosage of 500 micrograms per kg bodyweight, Qualimec Cattle Pour-on controls infections acquired with *Trichostrongylus axei* and *Cooperia spp.* up to 14 days after treatment, but only in case of group treatment; *Ostertagia ostertagi* and *Oesophagostomum radiatum* up to 21 days after treatment; *Dictyocaulus viviparus* up to 28 days after treatment.

Occasionally variable activity may be observed against *Haemonchus placei* (L4), *Cooperia* spp., *Trichostrongylus axei*, *Trichostrongylus colubriformis*.

Qualimec Cattle Pour-on also controls horn fly (*Haematobia irritans*) for 28 days, partial efficacy may last for up to 35 days post application.

Studies have demonstrated that first-season grazing calves turned out to pasture in late April or May and treated 3, 8 and 13 weeks after turn-out can be protected 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.

4.3 Contraindications

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

Do not use in lactating dairy cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers, within 60 days of calving.

4.4 Special warnings for each target species

Do not treat cattle when their hide is wet.

Do not treat cattle if rain is expected, as rain within 2 hours of treatment may reduce efficacy.

Do not apply to areas of skin which have mange scabs or other lesions, or to areas contaminated with mud or manure.

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.

4.5 Special precautions for use

Special precautions for use in animals

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions may occur. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

It is recommended to treat all animals within a herd or group.

The shedding of nematode eggs can continue for some time after treatment.

Frequent and repeated use may lead to the development of resistance. 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.

Close container after use.

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

May be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons.

Operators should wear rubber gloves, boots, goggles and a waterproof coat when applying the product. Protective clothing should be washed after use.

As absorption through skin can occur, in the event of accidental skin contact, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

Do not smoke, eat or drink while handling the product.

Wash hands after use.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves and protective clothing should be worn when handling the veterinary medicinal product by women of childbearing age.

Use only in well ventilated areas or outdoors.

Highly inflammable, keep away from heat, sparks, open flame or other sources of ignition.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have shown neither embryotoxic nor teratogenic effects with ivermectin.

Can be used during pregnancy and lactation provided that the milk is not intended for human consumption.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Please also see section 4.3.

4.8 Interaction with other medicinal products and other forms of interactions

Do not combine ivermectin treatment with vaccination against lungworms. 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

Bodyweight should be assessed as accurately as possible before calculating the dosage.

Dosage

1ml per 10kg body weight (based on a recommended dosage level of 500 micrograms per kg body weight).

Administration

For topical application.

The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

The 250 ml and 1.0 litre packs must be used with appropriate dosing equipment.

Instructions for using the dispensing chamber:

- a) Take dip tube and insert end into base of measuring cap with slotted end going to the bottom of the container.
- b) Remove shipping cap from container.
- c) Screw measuring cap onto container.
- d) Select the correct dose rate by rotating the adjuster cap in either direction to position the dose indicator to the appropriate dose. Gently squeeze the bottle to fill to level (any excess will return to the bottle) and then tip and apply to animal along backline.

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

No signs of toxicity appeared in trials up to 3 times the recommended dose rate.

Clinical symptoms of ivermectin toxicity include ataxia and depression. No antidote has been identified. In case of overdose, symptomatic treatment should be given.

4.11 Withdrawal period(s)

Meat and offal: 28 days. Do not use in lactating cattle producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers, within 60 days of calving.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Ivermectin is a mixture of two compounds belonging to the avermectin family, which are a macrocyclic lactone group of endectocides. Avermectin is a microbial metabolite of the soil organism *Streptomyces avermilitis*.

ATC vet code: QP54AA01. Therapeutic group: endectocide.

5.1 Pharmacodynamic properties

It is generally accepted that ivermectin exerts its action in two main ways, interference with neurotransmission and opening chloride ion channels. The effect of ivermectin on the parasitic CNS is considered to operate through glutamate-mediated chloride channels. 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 opening of pre-synaptic chloride ion channels results in an efflux of chloride ions and depolarisation of the nerve terminal. These effects interfere with normal neurotransmission between nerves and muscles, resulting in parasite paralysis and eventual death.

5.2 Pharmacokinetic particulars

After administration of Qualimec Pour-On, the ivermectin is absorbed through the skin into the circulation of the treated animal. The maximum concentration in plasma occurs around 70 hours after application. Peak concentrations of about 7 ng/ml are obtained.

The residual antiparasitic effect of ivermectin is due to its persistence, which in turn is due in part to its long intrinsic half-life ($t_{1/2\beta}$ of approximately 210 hours), in part to its relatively high plasma protein binding (80% in cattle; binding remains relatively constant over time) and in part to the nature and type of the ivermectin formulation. Elimination is in the faeces (via biliary excretion). Over 60% of the dose is excreted after 3 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol
Polypropoxylate-2-myristyl ether propionate
N-methyl-2-pyrrolidone
Benzyl Alcohol (E1519)
Water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

Shelf-life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

Protect from direct light. Store in tightly closed, original container.

6.5 Nature and composition of immediate packaging

250 ml white non-fluorinated or fluorinated high-density polyethylene bottle with a drawing tube and measuring device.

1.0 L white non-fluorinated or fluorinated high-density polyethylene bottle with a drawing tube and measuring device.

2.5 L white non-fluorinated or fluorinated high-density polyethylene back-pack with polypropylene strap and vented cap

5.0 L white non-fluorinated or fluorinated high-density polyethylene back-pack with polypropylene strap and vented cap.

Closure: White polypropylene screw-cap.

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

The product is extremely dangerous to fish and aquatic life. Do not contaminate surface water or ditches with product or the used container. Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

ECO Animal Health Europe Limited
6th Floor
South Bank House
Barrow Street
Dublin 4
D04 TR29
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22693/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 May 2001

Date of last renewal: 02 August 2006

10 DATE OF REVISION OF THE TEXT

12/09/2023