SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qualimec 5 mg/ml Pour-on Solution for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance(s):
Ivermectin (E1519) 5 mg

Excipient(s):
Benzyl alcohol 10 mg
N-methyl pyrrolidone 35 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pour-on solution.
A clear, colourless 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 -
Haemonchus placei (adult andL4)
Ostertagia ostertagi (adult and L4, including inhibited larvae)
Trichostrongylus axei (adult and L4)
Trichostrongylus colubriformis (adult and L4)
Cooperia punctata (adult only)
Cooperia oncophora (adult only)
Strongyloides papillosus (adult only)
Oesophagostomum radiatum, (adult and L4)

Lungworm (adult and L4) – *Dictyocaulus viviparus*.

Warbles (parasitic stages) – *Hypoderma bovis*, *Hypoderma lineatum*.

Mange mites – *Sarcoptes scabiei var. bovis*. The product may also be used to reduce infection of the mange mite *Chorioptes bovis,* but complete elimination may not occur.

Sucking and biting lice – *Linognathus vituli*, *Haematopinus eurysternus*, *Bovicola (Damalinia) bovis.*

The product has persistent activity against infections acquired with *Trichostrongylus axei* and *Cooperia spp.* up to 14 days after treatment, but only in the case of group treatment; *Ostertagia ostertagi* and *Oesophagostomum radiatum* up to 21 days after treatment; *Dictyocaulus viviparus* up to 28 days after treatment. It also has persistent activity against horn flies (*Haematobia irritans*) for up to 28 days after treatment; partial efficacy against *Haematobia irritans* may last for up to 35 days post application.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.
The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions including fatalities in dogs, may occur.

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.

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 *Ostertagia ostertagi* in cattle. 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

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
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. Do not allow these species to come in contact with this product.

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

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

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.

Use only in well ventilated areas or outdoors.
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.

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 4.11

4.8 Interaction with other medicinal products and other forms of interaction

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

To ensure administration of a correct dose, body weight should be determined as accurately as possible.
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.

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.
e) 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: 31 days.
Milk: Not permitted for 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 PROPERTIES

ATC vet code: QP54AA01.

Pharmacotherapeutic group: endectocides, avermectins

5.1 Pharmacodynamic 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*.

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 the product, 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-Methylpyrrolidone
Benzyl Alcohol (E1519)
Water

6.2 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

Do not store above 25°C.

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

Keep the container in the outer carton.

If stored at temperatures below 0°C, the solution may appear cloudy. Allowing to warm at room temperature will restore normal appearance without affecting efficacy.

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.

Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Eco Animal Health Ltd.
The Grange
100 High Street
London
N14 6BN
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 13277/4022

9. DATE OF FIRST AUTHORISATION

29 July 2008

10. DATE OF REVISION OF THE TEXT

September 2024

Approved 18 September 2024
Gavin Hall