LABEL

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qualimec 5 mg/ml Pour-on Solution for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 0.5% w/v ivermectin as active ingredient and 1.0% w/v benzyl alcohol as preservative.

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

250 ml
1.0 l
2.5 l

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For treatment of gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice of beef and non-lactating dairy cattle.

Read the carton/package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

1 ml/10 kg body weight (based on a recommended dosage level of 500 μg/kg body weight).
The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

Read the carton/package leaflet before use

8. WITHDRAWAL PERIOD

Cattle - Edible tissue: 28 days

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption. Do not use in pregnant heifers within 60 days prior to calving.

Read the carton/package leaflet before use

10. EXPIRY DATE

MM/YY
After first opening the container: 6 months.

11. SPECIAL STORAGE CONDITIONS

Close container after use
Store in tightly closed, original container.
Protect from direct light.
FLAMMABLE, keep away from heat, sparks, open flame or other sources of ignition.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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 local requirements.

13. THE WORDS FOR ANIMAL TREATMENT ONLY AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 13277/4022

17. MANUFACTURER'S BATCH NUMBER

LM

<Batch> <Lot> <BN> {number}

CARTON

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qualimec 5 mg/ml Pour-on Solution for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 0.5% w/v ivermectin as active ingredient and 1.0% w/v benzyl alcohol as preservative.

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

250 ml
1.0 l
2.5 l
5.0 l

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment and control gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice of beef and non-lactating dairy Cattle.

Qualimec Cattle Pour-on at the recommended dosage level of 500 μg ivermectin per kg body weight effectively controls the following parasites of cattle.

Gastro-intestinal worms (adult and fourth stage larvae):
Haemononchus placei, Ostertagia ostertagi (including inhibited larvae)*, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia spp., Strongyloides papillosus* (adult)*, Oesophagostomum radiatum, Trichuris app.* (adult)

Lungworm (adult and fourth stage larvae):
Dictyocaulus viviparus

Warbles (parasitic stages):
Hypoderma bovis and *H. lineatum.*

Mange mites:
Sarcoptes scabiei var. bovis and *Chorioptes bovis*

Sucking and biting ice:
Linognathus vituli, Haematopinus eurysternus, and *Damalinia bovis.*

Given at the dosage of 500 μg 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. It also controls horn flies (*Haematobia irritants*) for up to 35 days after treatment.

To obtain optimal benefit from the persistent activity for grazing animals, it is recommended that calves which are set-stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Administration
For topical application to cattle
The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

The 250ml, 1 and 2.5 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.

8. WITHDRAWAL PERIOD

Cattle - Edible tissue: 28 days

9. SPECIAL WARNING(S), IF NECESSARY

- Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption.
- Do not use in pregnant heifers within 60 days prior to calving.
- Do not treat cattle when their hide or hair 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.
- Can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. Qualimec Cattle Pour-on will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.
- Qualimec Cattle Pour-on has been formulated for use in cattle. It is not recommended for other species as adverse reactions, including fatalities in dogs may occur.
- Do not combine treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be done within a period of 28 days before or after vaccination.
- It is recommended to treat all animals within herd or group.
- The shedding of nematode eggs can continue for some time after treatment.
- In case of treatment of warble-infections animals should not be treated when larvae stages are present in the oesophagus wall or near the spinal cord.
- If stored at temperatures below 0°C, Qualimec Cattle Pour-on may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.
- 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 and boots with a waterproof coat when applying the product.
- Protective clothing should be washed after use.
- If accidental skin contact occurs, 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 or eat while handling the product.
- Wash hands after use.
- Use only in well ventilated areas or outdoors.

10. EXPIRY DATE

MM/YY
After first opening the container: 6 months.

11. SPECIAL STORAGE CONDITIONS

- Protect from direct light.
- Close container after use.
- Store in tightly closed, original container.
- FLAMMABLE, keep away from heat, sparks, open flame or other sources of ignition.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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 local requirements.

13. THE WORDS FOR ANIMAL TREATMENT ONLY AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 13277/4022

17. MANUFACTURER'S BATCH NUMBER

LM

<Batch> <Lot> <BN> {number}

PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Qualimec 5 mg/ml Pour-on Solution for Cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
ECO Animal Health Ltd.
The Grange
100 High Street
London
N14 6BN
United Kingdom

Manufacturer for the batch release
Acme Drugs s.r.l.
Via Portella della Ginestra, 9/a,
Zona Industriale Corte Tegge,
42025 CAVRIAGO (RE),
Italy
Tel: +39 0522.941919
E-Mail: info@acmedrugs.com
Authorisation Number: 27/2016 / V.

or

Safapac Ltd.
4 Stapleton Road
Orton Southgate
Peterborough, PE2 6TB
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qualimec 5 mg/ml Pour-on Solution for Cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Contains 0.5% w/v ivermectin as active ingredient and 1.0% w/v benzyl alcohol as preservative.

4. INDICATION(S)

For the treatment and control gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice of beef and non-lactating dairy Cattle.

Qualimec Cattle Pour-on at the recommended dosage level of 500 μg ivermectin per kg body weight effectively controls the following parasites of cattle.

Gastro-intestinal worms (adult and fourth stage larvae):
Haemononchus placei, Ostertagia ostertagi (including inhibited larvae)*, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia spp., Strongyloides papillosus* (adult)*, Oesophagostomum radiatum, Trichuris app.* (adult)

Lungworm (adult and fourth stage larvae):
Dictyocaulus viviparus

Warbles (parasitic stages):
Hypoderma bovis and *H. lineatum.*

Mange mites:
Sarcoptes scabiei var. bovis and *Chorioptes bovis*

Sucking and biting ice:
Linognathus vituli, Haematopinus eurysternus, and *Damalinia bovis.*

Given at the dosage of 500 μg 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. It also controls horn flies (*Haematobia irritants*) for up to 35 days after treatment.

To obtain optimal benefit from the persistent activity for grazing animals, it is recommended that calves which are set-stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. 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.

5. CONTRAINDICATIONS

Do not use in case of known hypersensitivity to the active ingredient.
Do not administer by intravenous or intramuscular route.
Do not use in dairy cows, during lactation or the dry period, and in beef cows during the lactation period when milk is intended for human consumption.
Do not use in pregnant heifers within 60 days prior to calving

6. ADVERSE REACTIONS

None known

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and administration

Dosage

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

Administration

For topical application to cattle

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

The packs must be used with appropriate dosing equipment.
Instructions for using the dispensing chamber for 250 ml and 1 litre

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.
a) Select the correct dose rate by rotating the adjuster cap in either direction to position the dose indicator to the appropriate dose.
b) Gently squeeze the bottle to fill to level (any excess will return to the bottle) and then tip and apply to animal along backline.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

Cattle - Edible tissue: 28 days

11. SPECIAL STORAGE PRECAUTIONS

Protect from direct light.
The expiry date should be not more than 36 months from the date of manufacture.
Product must be used within 6 months of opening.
Close container after use.
Store in tightly closed, original container.
FLAMMABLE, keep away from heat, sparks, open flame or other sources of ignition.

12. SPECIAL WARNING(S)

- Do not use in dairy cows, during lactation or the dry period, when milk is intended for human consumption.
- Do not use in pregnant heifers within 60 days prior to calving.
- Do not treat cattle when their hide or hair 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.
- Can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. Qualimec Cattle Pour-on will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.
- Qualimec Cattle Pour-on has been formulated for use in cattle. It is not recommended for other species as adverse reactions, including fatalities in dogs may occur.
- Do not combine treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be done within a period of 28 days before or after vaccination.
- It is recommended to treat all animals within herd or group.
- The shedding of nematode eggs can continue for some time after treatment.
- In case of treatment of warble-infections animals should not be treated when larvae stages are present in the oesophagus wall or near the spinal cord.
- If stored at temperatures below 0°C, Qualimec Cattle Pour-on may appear cloudy. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.
- Ataxia and depression may occur as adverse reactions by overdosing
- 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 and boots with a waterproof coat when applying the product.
- Protective clothing should be washed after use.
- If accidental skin contact occurs, 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 or eat while handling the product.
- Wash hands after use.
- Use only in well ventilated areas or outdoors.
- For animal treatment only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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 local requirements.

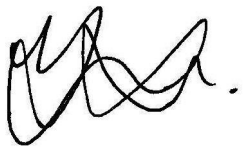
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2023

VPA22693/004/001

Legal Category: LM Licensed Merchant

Package Quantities: 250 ml, 1.0 l, 2.5 l, 5.0 l



Approved: 01 June 2023