

LABEL

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 5 mg/ml Pour-on Solution for Cattle
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance(s):
Ivermectin.....5 mg
Excipient(s):
Benzyl alcohol (E1519)....10 mg

3. PHARMACEUTICAL FORM

Pour-on solution
A clear, colourless solution

4. PACKAGE SIZE

250 ml
1.0 l
2.5 l
5.0 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

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

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the carton/package leaflet before use

10. EXPIRY DATE

MM/YY

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

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from light.

Store in the original container, tightly closed.

Keep the container in the outer carton.

Once broached, use by: _____

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 veterinary medicinal product or waste material derived from such veterinary medicinal product 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 SIGHT AND REACH OF CHILDREN.

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder - Ireland
ECO Animal Health Europe Limited
6th Floor, South Bank House
Barrow Street
Dublin 4, D04 TR29
Ireland

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

16. MARKETING AUTHORISATION NUMBER(S)

VPA22693/003/001
Vm 13277/4021

17. MANUFACTURER'S BATCH NUMBER

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

CARTON

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 5 mg/ml Pour-on Solution for Cattle
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance(s):

Ivermectin.....5 mg

Excipient(s):

Benzyl alcohol (E1519).....10 mg

N-methyl pyrrolidone..... 35 mg

3. PHARMACEUTICAL FORM

Pour-on solution
A clear, colourless solution

4. PACKAGE SIZE

250 ml

1.0 l

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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 andL4)

Trichostrongylus colubriformis (adult andL4)

Cooperia punctata (adult only)

Cooperia oncophora (adult only)

Strongyloides papillosus (adult only)

Oesophagostomum radiatum, (adult andL4)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical application. Pour-on

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

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

The 250 ml (or 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.

8. WITHDRAWAL PERIOD(S)

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.

9. SPECIAL WARNING(S), IF NECESSARY

Special precautions for use in animals

- As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.
- 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 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. Do not allow these species to come in contact with the 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.
- 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.
- 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

- Close container after use

Operator warnings

- The product 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 irritation persists, seek medical advice and show the package label to the doctor.
- 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.
- 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.
- HIGHLY INFLAMMABLE, keep away from heat, sparks, open flame or other sources of ignition.

Use during Pregnancy

- 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.

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.

10. EXPIRY DATE

MM/YY

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

11. SPECIAL STORAGE CONDITIONS

- Do not store above 25°C.
- Protect from light.
- Store in the original container, tightly closed.
- Keep the container in the outer carton.
- Once broached, use by: _____
- 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.

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 veterinary medicinal product or waste material derived from such veterinary medicinal product 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 SIGHT AND REACH OF CHILDREN.

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6th Floor, South Bank House
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ECO Animal Health Ltd.
The Grange
100 High Street
London
N14 6BN
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

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17. MANUFACTURER'S BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 5 mg/ml Pour-on Solution for Cattle
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance(s):

Ivermectin.....5 mg

Excipient(s):

Benzyl alcohol (E1519).....10 mg

N-methyl pyrrolidone.....35 mg

3. PHARMACEUTICAL FORM

Pour-on solution
A clear, colourless solution

4. PACKAGE SIZE

2.5 l

5.0 l

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

Gastro-intestinal worms -

Haemonchus placei (adult andL4)

Ostertagia ostertagi (adult andL4, including inhibited larvae)

Trichostrongylus axei (adult andL4)

Trichostrongylus colubriformis (adult andL4)

Cooperia punctata (adult only)

Cooperia oncophora (adult only)

Strongyloides papillosus (adult only)

Oesophagostomum radiatum, (adult andL4)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical application. Pour-on

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

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

The 2.5 l packs must be used with appropriate dosing equipment.

8. WITHDRAWAL PERIOD(S)

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.

9. SPECIAL WARNING(S), IF NECESSARY

Special Precautions for use in animals

- As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.
- 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.
- 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. Do not allow these species to come in contact with the 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.
- 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.
- 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
- Close container after use.

Operator warnings

- The product 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 irritation persists, seek medical advice and show the package label to the doctor.
- 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.
- 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.
- Highly inflammable, keep away from heat, sparks, open flame or other sources of ignition.

Use during pregnancy

- 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.

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.

10. EXPIRY DATE

MM/YY

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

11. SPECIAL STORAGE CONDITIONS

- Do not store above 25°C.
- Protect from light.
- Store in the original container, tightly closed.
- Keep the container in the outer carton.
- Once broached, use by: _____
- 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.

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 veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with 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 SIGHT AND REACH OF CHILDREN.

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder - Ireland
ECO Animal Health Europe Limited
6th Floor, South Bank House
Barrow Street
Dublin 4, D04 TR29
Ireland

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

16. MARKETING AUTHORISATION NUMBER(S)

VPA22693/003/001
Vm 13277/4021

17. MANUFACTURER.S BATCH NUMBER

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

PACKAGE LEAFLET

**PACKAGE LEAFLET:
ECOMECTIN 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 in Ireland
ECO Animal Health Europe Limited
6th Floor, South Bank House
Barrow Street
Dublin 4, D04 TR29
Ireland

Marketing authorisation holder in the UK
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),
Italia
Tel: +39 0522.941919
E-Mail: info@acmedrugs.com
Authorisation Number: 27/2016 / V.

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ECOMECTIN 5 MG/ML POUR-ON SOLUTION FOR CATTLE
Ivermectin

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

1 ml contains:

Active substance(s):

Ivermectin.....5 mg

Excipient(s):

Benzyl alcohol (E1519).....10 mg

N-methyl pyrrolidone.....35 mg

4. INDICATION(S)

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

Gastro-intestinal worms -

Haemonchus placei (adult andL4)

Ostertagia ostertagi (adult andL4, including inhibited larvae)

Trichostrongylus axei (adult andL4)

Trichostrongylus colubriformis (adult andL4)

Cooperia punctata (adult only)

Cooperia oncophora (adult only)

Strongyloides papillosus (adult only)

Oesophagostomum radiatum, (adult andL4)

Lungworm (adult andL4) – *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.

5. 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

6. ADVERSE REACTIONS

None known

7. TARGET SPECIES

Cattle

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

For topical application. Pour-on

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

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:

- 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.
- c) Select the correct dose rate by rotating the adjuster cap in either direction to position the dose indicator to the appropriate dose.
- d) 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

- As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.
- It is recommended to treat all animals within a herd or group.
- 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.
- 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.

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

- Do not store above 25°C.
- Protect from light.
- Store in the original container, tightly closed.
- Keep out of reach and sight of children
- Shelf-life after first opening the immediate packaging: 6 months
- When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label
- 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.

12. SPECIAL WARNING(S)

Special precautions for use in animals

- 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 the product.
- The shedding of nematode eggs can continue for some time after treatment.
- Close container after use.

Operator warnings

- The product 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 irritation persists, seek medical advice and show the package label to the doctor.
- 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.
- Highly inflammable, keep away from heat, sparks, open flame or other sources of ignition.
- 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 during pregnancy

- 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.

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.

Overdose

- 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.

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 veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

Pack sizes: 250ml, 1.0l, 2.5l, 5.0l
Not all pack sizes may be marketed.

Approved: 30 July 2024

Gavin Hall