

A. SYRINGE LABEL

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Promec 18.7 mg/g Oral Paste for Horses
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g

3. PHARMACEUTICAL FORM

Oral Paste

4. PACKAGE SIZE

6.42 g or 7.49 g

5. TARGET SPECIES

Horses

6. INDICATION(S)

Antiparasitic treatment for Horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet or outer carton before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 34 days
Do not use in mares producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP MM/YYYY

The product is for single use. After use the syringe should be discarded

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

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

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13277/4029

17. MANUFACTURER’S BATCH NUMBER

Lot

B. BOX LABEL

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box containing 1 syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Promec 18.7 mg/g Oral Paste for Horses
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

1 Syringe containing 7.49 g (6.42 g) paste which contains 18.7 mg/g ivermectin

3. PHARMACEUTICAL FORM

Oral Paste

4. PACKAGE SIZE

6.42 g or 7.49g

5. TARGET SPECIES

Horses

6. INDICATION(S)

Antiparasitic treatment for Horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

One syringe will treat up to a 700kg horse (only for 7.49 g syringe)
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 34 days
Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use for full instructions and user warnings

10. EXPIRY DATE

(EXP) MM/YYYY

The product is for single use. After use the syringe should be discarded.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

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

Disposal: read package leaflet.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13277/4029

17. MANUFACTURER’S BATCH NUMBER

Lot

C. PACKAGE LEAFLET

PACKAGE LEAFLET

Promec 18.7 mg/g Oral Paste for Horses

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, Zona Industriale Corte Tegge
42025 CAVRIAGO (RE)
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Promec 18.7 mg/g Oral Paste for Horses
Ivermectin

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

Each g contains:

Active substance:

Ivermectin 18.7 mg

Excipients:

Titanium dioxide (E171) 20 mg

A white homogeneous paste

4. INDICATION(S)

Treatment of nematode or arthropod infection due to:

Large strongyles:

Strongylus vulgaris (adults and L₄ stage larvae [arterial])

Strongylus edentatus (adults and L₄ stage larvae [tissue])

Strongylus equinus (adults)

Small strongyles (including benzimidazole resistant strains):

Cyathostomum spp. (adults and luminal L₄ stage larvae)

Cylicocyclus spp. (adults and luminal L₄ stage larvae)

Cylicodontophorus spp. (adults and luminal L₄ stage larvae)
Cylicostephanus spp. (adults and luminal L₄ stage larvae)
Gyalocephalus spp. (adults and luminal L₄ stage larvae)

Ascarids:

Parascaris equorum (luminal L₅ larvae and adults)

Pinworms:

Oxyuris equi (L₄ stage larvae and adults)

Neck threadworms:

Onchocerca spp. (microfilariae)

Stomach bots:

Gasterophilus spp. (oral and gastric stages)

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in dogs or cats as severe adverse reactions may occur.

6. ADVERSE REACTIONS

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses

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

Dosage:

One syringe division of paste per 100 kg body weight (based on a recommended dosage of 200 microgram ivermectin per kg body weight). The syringe containing 6.42 g of paste delivers sufficient paste to treat 600 kg of bodyweight at the recommended dose rate.

The syringe containing 7.49 g of paste delivers sufficient paste to treat 700 kg of bodyweight at the recommended dose rate.

Administration:

The paste is given by oral route.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible. The animal's mouth should be free from food to ensure swallowing. Turn the screw gauge on the syringe plunger to the body weight of the horse. The tip of the syringe barrel should be inserted at the interdental space (the

gap between the front and back teeth) and the paste deposited on the base of the tongue. Advance the plunger as far as it will go, depositing the medication on the base of the tongue. Immediately elevate the horse's head for a few seconds to ensure swallowing.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 34 days

Do not use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children

Do not store above 25°C

The product is for single use. After use, the syringe should be discarded.

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton after {EXP}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals

The effects of GABA agonists are increased by ivermectin.

Some horses with heavy infections of *Onchocerca* spp. microfilariae have experienced oedema and pruritus following treatment. Such reactions are assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable

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 or misadministration of the product.

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.

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. In the event that a product is suspected of being ineffective, the animal owner is advised to seek veterinary advice.

Resistance to ivermectin has been reported in *Parascaris equorum*. Therefore, the use of this product should be based on local farm epidemiological information about

susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics

Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

Dogs and cats should not be allowed to ingest spilled gel or have access to used packaging due to the potential for adverse effects related to ivermectin toxicity

The product has been formulated for use in horses only. Cats, dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also turtles and tortoises may be adversely affected by the concentration of ivermectin in this product if they are allowed to ingest spilled paste or have access to used syringes.

The product can be administered to mares at any stages of pregnancy or lactation. Do not use in mares producing milk for human consumption.

Mild transitory signs (slowed pupillary light response and depression) have been seen at a higher dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis (dilation of the pupil), ataxia (incoordination), tremors (shaking), stupor (dull), coma and death. The less severe signs have been transitory.

Although no antidote has been identified, symptomatic therapy may be beneficial.

User warnings

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

Wash hands after use.

This product may cause skin and eye irritation. Therefore, the user should avoid contact of the product with the skin and the eyes. In case of contact, rinse immediately with plenty of water.

In the case of accidental ingestion or eye irritation after contact seek medical advice immediately and show the package insert or the label to the physician.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container. Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2023

15. OTHER INFORMATION

For Animal Treatment Only

Pack size:

Box containing 1 syringe of 6,42 g

Box containing 1 syringe of 7,49 g

Box containing 50 syringes of 7,49 g

Not all pack sizes may be marketed

B. BOX LABEL
Box of 50 syringes

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box containing 50 syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Promec 18.7 mg/g Oral Paste for Horses
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g
A white homogeneous paste

3. PHARMACEUTICAL FORM

Oral Paste

4. PACKAGE SIZE

Each syringe containing 7.49 g paste which contains 18.7 mg/g ivermectin
Carton box containing 50 syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

Treatment of nematode or arthropod infection due to:

Large strongyles:

Strongylus vulgaris (adults and L₄ stage larvae [arterial])

Strongylus edentatus (adults and L₄ stage larvae [tissue])

Strongylus equinus (adults)

Small strongyles (including benzimidazole resistant strains):

Cyathostomum spp. (adults and luminal L₄ stage larvae)

Cylicocyclus spp. (adults and luminal L₄ stage larvae)

Cylicodontophorus spp. (adults and luminal L₄ stage larvae)

Cylicostephanus spp. (adults and luminal L₄ stage larvae)

Gyalocephalus spp. (adults and luminal L₄ stage larvae)

Ascarids:

Parascaris equorum (luminal L₅ larvae and adults)

Pinworms:

Oxyuris equi (L₄ stage larvae and adults)

Neck threadworms:
Onchocerca spp. (microfilariae)

Stomach bots:
Gasterophilus spp. (oral and gastric stages)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage:

One syringe division of paste per 100 kg body weight (based on a recommended dosage of 200 microgram ivermectin per kg body weight).

The syringe containing 7.49 g of paste delivers sufficient paste to treat 700 kg of bodyweight at the recommended dose rate.

Administration:

The paste is given by oral route.

To ensure administration of a correct dose, body weight should be determined as accurately as possible. The animal's mouth should be free from food to ensure swallowing. Turn the screw gauge on the syringe plunger to the body weight of the horse. The tip of the syringe barrel should be inserted at the interdental space (the gap between the front and back teeth) and the paste deposited on the base of the tongue. Advance the plunger as far as it will go, depositing the medication on the base of the tongue. Immediately elevate the horse's head for a few seconds to ensure swallowing.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods(s)

Meat and offal: 34 days

Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in dogs or cats as severe adverse reactions may occur.

Adverse reactions

The effects of GABA agonists are increased by ivermectin

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Special precautions for use in animals

Some horses with heavy infections of *Onchocerca* spp. microfilariae have experienced oedema and pruritus following treatment. Such reactions are assumed

to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable

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 or misadministration of the product.

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.

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. In the event that a product is suspected of being ineffective, the animal owner is advised to seek veterinary advice.

Resistance to ivermectin has been reported in *Parascaris equorum*. Therefore, the use of this product should be based on local farm epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics

Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

Dogs and cats should not be allowed to ingest spilled gel or have access to used packaging due to the potential for adverse effects related to ivermectin toxicity

The product has been formulated for use in horses only. Cats, dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also turtles and tortoises may be adversely affected by the concentration of ivermectin in this product if they are allowed to ingest spilled paste or have access to used syringes.

The product can be administered to mares at any stages of pregnancy or lactation. Do not use in mares producing milk for human consumption.

Mild transitory signs (slowed pupillary light response and depression) have been seen at a higher dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis (dilation of the pupil), ataxia (incoordination), tremors (shaking), stupor (dull), coma and death. The less severe signs have been transitory.

Although no antidote has been identified, symptomatic therapy may be beneficial.

User warnings

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

Wash hands after use.

This product may cause skin and eye irritation. Therefore, the user should avoid contact of the product with the skin and the eyes. In case of contact, rinse immediately with plenty of water.

In the case of accidental ingestion or eye irritation after contact seek medical advice immediately and show the package insert or the label to the physician.

10. EXPIRY DATE

(EXP) MM/YYYY

The product is for single use. After use the syringe should be discarded.

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton after {EXP}. The expiry date refers to the last day of that month.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container. Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

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

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, Zona Industriale Corte Tegge

42025 CAVRIAGO (RE)

Italy

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13277/4029

17. MANUFACTURER'S BATCH NUMBER

Lot XXXX

Pack sizes:

Box containing 1 syringe of 6,42 g

Box containing 1 syringe of 7,49 g

Box containing 50 syringes of 7,49 g

Not all pack sizes may be marketed.

Approved 02 June 2023

