PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROMEC 18.7 mg/g Oral Paste for Horses

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:
Ivermectin 18.7 mg

3. PACKAGE SIZE

6.42 g
7.49 g
50 x 7.49 g

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral paste

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 34 days
Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy }
Once opened use immediately

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

ACME DRUGS s.r.l.

14. MARKETING AUTHORISATION NUMBERS

Vm 61301/5004 (GB)
Vm 61301/3004 (NI)

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROMEC

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each g of paste contains 18.7 mg of ivermectin

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. mm/yyyy

Once opened use immediately.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

PROMEC 18.7 mg/g oral paste for Horses

2. Composition

Each g contains:

Active substance:
Ivermectin 18.7 mg

Excipients:
Titanium dioxide (E171) 20 mg

White homogeneous paste

3. Target species

Horses

4. Indications for use

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. Special warnings

Special warnings:

Some horses with heavy infections of *Onchocerca* spp. microfilariae have experienced oedema (swelling) and pruritus (itching) 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

Special precautions for safe use in the target species:

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.

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

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

Wash hands after use.
This veterinary medicinal product may cause skin and eye irritation. Therefore, the user should avoid contact of the veterinary medicinal 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 leaflet or the label to the physician.

Other precautions:

Dogs and cats should not be allowed to ingest spilled paste or have access to used packaging due to the potential for adverse effects related to ivermectin toxicity. The veterinary medicinal 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 veterinary medicinal product if they are allowed to ingest spilled paste or have access to used syringes.

Pregnancy and lactation:

Can be used during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:

The effects of GABA agonists are increased by ivermectin.

Overdose:

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.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Horses

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder

using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Dosage:
One syringe division of paste/100 kg body weight (based on a recommended dosage of 0.2 mg 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 a correct dosage, 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 periods

Meat and offal: 34 days
Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Shelf life after first opening the immediate packaging: use immediately.

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 precautions for disposal

The veterinary medicinal product should not enter water courses as ivermectin is EXTREMELY DANGEROUS TO FISH AND OTHER AQUATIC ORGANISMS.
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 61301/5004 (GB)
Vm 61301/3004 (NI)

Pack size:

Carton box with 1 syringe of 6.42 g
Carton box with 1 syringe of 7.49 g
Carton box with 50 syringes of 7.49 g

Not all pack sizes may be marketed

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.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

ACME DRUGS s.r.l.
Via Portella della Ginestra 9
42025 Cavriago
Italy
Tel +39 0522 942780
pharmacovigilance@acmedrugs.eu

17. Other information

POM-VPS

Gavin Hall
Approved: 15 May 2026