

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec 18.7 mg/g oral paste

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g

3. PACKAGE SIZE

Oral syringe application – 6.42 g
Oral syringe application – 24 x 6.42 g

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 21 days.
Milk: Not permitted for use in lactating mares producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

Bimeda Animal Health Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 50146/5008

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{SYRNIGES}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Cyathostomum spp.

Cyathostomum catinatum
Cyathostomum pateratum

Cylicocyclus spp.

Cylicocyclus ashworthi
Cylicocyclus elongatus
Cylicocyclus insigne
Cylicocyclus leptostomum
Cylicocyclus nassatus
Cylicocyclus radiatus

Cylicostephanus spp.

Cylicostephanus asymmetricus
Cylicostephanus bidentatus
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus

Cylicodontophorus spp.

Cylicodontophorus bicornatus

Gyalocephalus capitatus

Parapoteriostomum spp.

Parapoteriostomum euproctus
Parapoteriostomum mettami

Petrovinema spp.

Petrovinema poculatum

Poteriostomum spp.

Poteriostomum imparidentatum

Lungworms (adult and immatures)

Dictyocaulus arnfieldi

Pinworms (adult and immatures)

Oxyuris equi

Ascarids (adults and third & fourth stage larvae)

Parascaris equorum

Hairworms (adults)

Trichostrongylus axei

Large-mouth stomach worms (adults)

Habronema muscae

Neck threadworms (microfilariae)

Onchocerca spp.

Intestinal threadworms (adults)

Strongyloides westeri

Stomach bots

Oral and gastric stages of *Gastrophilus* spp.

5. Contraindications

This veterinary medicinal product has been formulated specifically for use in horses only. Dogs and cats 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.

6. Special warnings

Special warnings:

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 bodyweight 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.

Resistance to ivermectin (an avermectin) has been reported in *Parascaris equorum* in horses in a number of countries, including the EU. Therefore, the use of this veterinary medicinal product should be based on local (regional, 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:

Where there is significant tissue damage following *Habronema* infestation, additional medical therapies may be required.

Dogs and cats 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.

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

Do not smoke, drink or eat while handling this veterinary medicinal product.
Wash hands after use. For veterinary use only. Keep out of the reach and sight of children.

Special precautions for the protection of the environment:

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container.

Pregnancy and lactation:

Can be used during pregnancy. Horses of all ages, including pregnant mares and breeding stallions, have been treated with no adverse effect. For use in lactating mares please see 'Withdrawal periods'.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

Mild transitory signs (slowed pupillary light response and depression) have been seen at a dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses includes mydriasis, ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. No antidote has been identified; however, symptomatic therapy may be beneficial.

Major incompatibilities:

No major incompatibility has been identified.

Do not mix with other veterinary medicinal products.

7. Adverse events

Horses:

Undetermined frequency (cannot be estimated from the available data): Oedema¹, Pruritus¹

¹Some horses carrying heavy infection of *Onchocerca* microfilariae have experienced oedema and pruritus following dosing, 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.

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

Administer orally as a single dose rate to horses at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight. This syringe contains sufficient paste to treat one 600 kg horse at the recommended dose rate (200 mcgs of ivermectin per kg of bodyweight).

Dosing Instructions:

Each weight marking on the syringe plunger will deliver sufficient paste to treat 100 kg bodyweight. Unlock the knurled ring by making ¼ turn and slide the knurled ring up the plunger shaft so that the side nearest the barrel is at the prescribed weight marking. Turn

the knurled ring $\frac{1}{4}$ turn to lock in place. Make sure the horse's mouth contains no feed. Remove the plastic cap from the tip of the nozzle. Insert the syringe into the horse's mouth at the interdental space. Advance the plunger as far as it will go, depositing the medication on the base of the tongue. Immediately raise the horse's head for a few seconds after dosing.

9. Advice on correct administration

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

Parasite control program: All horses should be included in a regular parasite control program, with particular attention being paid to mares, foals and yearlings. Resistance to ivermectin has been reported in *Parascaris equorum* in horses in a number of countries, including the EU. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

10. Withdrawal periods

Meat and offal: 21 days.

Milk: Not permitted for use in lactating mares producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50146/5008

Dose graduated disposable polyethylene oral syringe containing 6.42 g of a yellow gel-like, apple flavoured, paste of uniform consistency.

The syringe is packed into an individual cardboard carton which in turn is packed into an outer display carton containing 24 packed syringes.

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 contact details to report suspected adverse reactions:

Bimeda Animal Health Limited,
Unit 2/3/4 Airtton Close,
Tallaght,
Dublin 24
Tel.: +353 1 4667900

Manufacturer responsible for batch release:

Provet S.A.
Nikiforou Foka & Agion Anargyron,
Thesi Vrago, Aspropyrgos, Attiki 19300
Greece

Local representative:

Eli Lilly and Company Limited
Elanco Animal Health
Priestley Road
Basingstoke
Hampshire
RG24 9NL
UK

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-
VPS

Ivermectin, the active ingredient of veterinary medicinal product is produced from a naturally occurring fungus (*Streptomyces avermitilis*). This veterinary medicinal product has a wide safety margin. At the recommended dosage, this veterinary medicinal product is completely reliable in foals, mares, ponies and horses. Pregnant mares can be treated with the paste at all stages of their pregnancy and the fertility of the treated stallions was not affected.

I *Gavin Hall*

Approved: 10 February 2026