[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec 18.7 mg/g oral paste for horses [NL, UK (NI)]
Bimectin 18,7 mg/g oral paste for horses [BE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Ivermectin 18.7 mg

Excipients:

Qualitative composition of excipients and other constituents
Maize Oil
Polysorbate 80
Colloidal Anhydrous Silica
Apple Flavour (In-house)

A yellow, gel-like paste of uniform consistency.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

This veterinary medicinal product is indicated for the treatment of parasitic infestations in horses due to:

Large strongyles
Strongylus vulgaris (adult and arterial larval stages)
Strongylus edentatus (adult and tissue larval stages)
Strongylus equinus (adults)
Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus
Craterostomum acuticaudatum (adults)

Small strongyles
Adult and immature (fourth stage larvae) small strongyles or *cyathostomes* including benzimidazole-resistant strains.
Coronocyclus spp.
Coronocyclus coronatus
Coronocyclus labiatus
Coronocyclus labratus
Cyathostomum spp.
Cyathostomum catinatum
Cyathostomum pateratum
Cylicocyclus spp.
Cylicocyclus ashworthi

Cylicocyclus elongatus
Cylicocyclus insigne
Cylicocyclus leptostomum
Cylicocyclus nassatus
Cylicocyclus radiatus
Cylicostephanus spp.
Cylicostephanus asymetricus
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.

3.3 Contraindications

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

3.4 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.

3.5 Special precautions for use

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 or 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.

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.

3.6 Adverse events

Horses:

Undetermined frequency (cannot be estimated from the available data)	Oedema[1], Pruritus[1]

[1]Some 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Administer orally as a single dose rate to horses at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight. Each syringe delivers 120 mg ivermectin, sufficient to treat 600 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 ¼ 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.

Parasite control program: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA01

4.2 Pharmacodynamics

Ivermectin is a member of the macrocyclic lactone class of endectocides, which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions and hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride and they do not readily cross the blood-brain barrier.

4.3 Pharmacokinetics

Following administration of veterinary medicinal product, ivermectin is rapidly absorbed to reach peak plasma concentration in several hours. This peak falls off gradually over several days. Ivermectin is eliminated primarily via the faeces. The highest residue levels are found in fat.

At a dose rate of 0.2 mg ivermectin per kilogram of bodyweight, plasma levels of ivermectin reach a mean C_{max} concentration of 40.44 ng/ml and a mean T_{max} at 8.35 hours. This peak falls off gradually to an average level of 3 ng/ml at 10 days.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

No major incompatibility has been identified.
Do not mix with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Dose graduated disposable polyethylene oral syringe containing 6.42 g of a yellow gel-like, apple flavoured, paste of uniform consistency.
Each syringe is packed into an individual cardboard carton which in turn is packed into an outer display carton containing 24 packed syringes.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24 July 2007

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec 18.7 mg/g oral paste [NL, UK (NI)]
Bimectin 18,7 mg/g oral paste [BE]

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

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec [NL, UK (NI)]
Bimectin [BE]

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Maximec 18.7 mg/g oral paste for horses [NL, UK (NI)]
Bimectin 18,7 mg/g oral paste for horses [BE]

2. Composition

Each gram contains:

Active substance:
Ivermectin 18.7 mg

A yellow, gel-like paste of uniform consistency.

3. Target species

Horses.

4. Indications for use

For broad spectrum use in parasite control for horses, ponies, mares and foals.
This veterinary medicinal product kills the adult and larval stages of most of the important internal parasites including small strongyles, the arterial stages of the large strongyles, lungworms and bots with a single dose. This veterinary medicinal product kills the small strongyles that are resistant to benzimidazole-based wormers.

This veterinary medicinal product controls the following horse parasites with one treatment:

Large strongyles
Strongylus vulgaris (adult and arterial larval stages)
Strongylus edentatus (adult and tissue larval stages)
Strongylus equinus (adults)
Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus
Craterostomum acuticaudatum (adults)

Small strongyles
Adult and immature (fourth stage larvae) small strongyles or *cyathostomes* including benzimidazole-resistant strains.
Coronocyclus spp.
Coronocyclus coronatus
Coronocyclus labiatus
Coronocyclus labratus
Cyathostomum spp.
Cyathostomum catinatum
Cyathostomum pateratum
Cylicocyclus spp.
Cylicocyclus ashworthi
Cylicocyclus elongatus
Cylicocyclus insigne

Cylicocyclus leptostomum
Cylicocyclus nassatus
Cylicocyclus radiatus
Cylicostephanus spp.
Cylicostephanus asymetricus
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): Oedema[1], Pruritus[1]
[1]Some 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:

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 ¼ 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

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. Date on which the package leaflet was last revised

03/2025

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

Manufacturer responsible for batch release:
Bimeda Animal Health Limited
Unit 2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information

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.