1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin 18.7 mg/g oral paste for horses [AT, DE, IE, FR]
Maximec 18.7 mg/g oral paste for horses [EL, IT, PT]
Maximec Equino 18.7 mg/g oral paste for horses [ES]
Maximec vet 18.7 mg/g oral paste for horses [DK]
Vectin 18.7 mg/g oral paste for horses [UK (NI)]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Ivermectin 18.7 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Maize oil	
Apple flavour	
Polysorbate 80	
Colloidal anhydrous silica	

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

For the treatment of nematode or arthropod infestations in horses due to:

Large strongyles
Strongylus vulgaris (adults and 4th larval [arterial] stages)
S. edentatus (adults and 4th larval [tissue] stages)
S. equinus (adults)
Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus

Small Strongyles
Adults and immatures (fourth stage larvae) small strongyles or cyathostomes unless otherwise stated.
Ivermectin is not effective against the encysted larval stages of the small strongyles.
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
Cylicostephanus spp.
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus
Cylicodontophorus spp.
Cylicodontophorus bicornatus
Parapoteriostomum spp.
Parapoteriostomum mettami
Petrovinema spp.
Petrovinema poculatum
Poteriostomum spp.

Lungworms (adult and inhibited fourth stage larvae)
Dictyocaulus arnfieldi

Pinworms (adult and inhibited fourth stage larvae)
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)
Gasterophilus spp.

3.3 Contraindications

None.

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 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 tests(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 *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 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:
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not eat, drink or smoke while handling the veterinary medicinal product. Avoid contact with skin and eyes. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and, if necessary, get medical attention.
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 product or used containers.

Other precautions:
The veterinary medicinal product has been formulated for use in horses only. Cats, dogs, especially Collies, Old English Sheepdogs and related breed 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.

3.6 Adverse events

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

[1]Experienced by some horses carrying heavy infection of *Onchocerca* microfilariae 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:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only according to benefit-risk assessment by the responsible veterinarian.
Studies performed in laboratory animals showed no teratogenic or embryotoxic effect of ivermectin at the recommended doses during therapy.
Please refer also to 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by ivermectin.

3.9 Administration routes and dosage

Oral use.
Administer orally as a single dose rate to horses at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight. The smaller syringe delivers 120 mg ivermectin, sufficient to treat 600 kg of bodyweight. The bigger syringe delivers 160 mg ivermectin, sufficient to treat 800 kg of bodyweight.
To ensure a correct dosage, 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.
This is a single dose product. Discard after use.

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.
The treatment schedule should be based on the local epidemiological situation.

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: 34 days.
Not authorised for use in animals 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. 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 the 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

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
To be used immediately after first opening the oral syringe.

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

High density polyethylene pre-filled dose-graduated disposable syringe containing 6.42 g (smaller syringe) or 8.56 g (bigger syringe) of product.

Pack sizes:
Cardboard box with 1 oral syringe of 6.42 g.
Cardboard box with 24 oral syringes of 8.56 g.
Cardboard box with 1 oral syringe 6.42 g.
Cardboard box with 24 oral syringes 8.56 g.

Not all pack sizes may be marketed.

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>.

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.

The veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms.

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: 05 September 2003

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

{MM/YYYY}

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin 18.7 mg/g oral paste [AT, DE, IE, FR]
Maximec 18.7 mg/g oral paste [EL, IT, PT]
Maximec Equino 18.7 mg/g oral paste [ES]
Maximec vet 18.7 mg/g oral paste [DK]
Vectin 18.7 mg/g oral paste [UK (NI)]

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 18.7 mg/g

3. PACKAGE SIZE

1 x 6.42 g
24 x 6.42 g
1 x 8.56 g
24 x 6.42 g

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral paste.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
To be used immediately after first opening the oral syringe.

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

Bimectin 18.7 mg/g oral paste for horses [AT, DE, IE, FR]
Maximec 18.7 mg/g oral paste for horses [EL, IT, PT]
Maximec Equino 18.7 mg/g oral paste for horses [ES]
Maximec vet 18.7 mg/g oral paste for horses [DK]
Vectin 18.7 mg/g oral paste for horses [UK (NI)]

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

Bimectin 18.7 mg/g oral paste for horses [AT, DE, IE, FR]
Maximec 18.7 mg/g oral paste for horses [EL, IT, PT]
Maximec Equino 18.7 mg/g oral paste for horses [ES]
Maximec vet 18.7 mg/g oral paste for horses [DK]
Vectin 18.7 mg/g oral paste for horses [UK (NI)]

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 the treatment of nematode or arthropod infestations in horses due to:

Large strongyles
Strongylus vulgaris (adults and 4th larval [arterial] stages)
S. edentatus (adults and 4th larval [tissue] stages)
S. equinus (adults)
Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus

Small Strongyles
Adults and immatures (fourth stage larvae) small strongyles or cyathostomes unless otherwise stated.
Ivermectin is not effective against the encysted larval stages of the small strongyles.
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
Cylicostephanus spp.
Cylicostephanus calicatus

Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus
Cylicodontophorus spp.
Cylicodontophorus bicornatus
Parapoteriostomum spp.
Parapoteriostomum mettami
Petrovinema spp.
Petrovinema poculatum
Poteriostomum spp.

Lungworms (adult and inhibited fourth stage larvae)
Dictyocaulus arnfieldi

Pinworms (adult and inhibited fourth stage larvae)
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)
Gasterophilus spp.

5. Contraindications

None.

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 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 tests(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 *Parascaris equorum* in horses. 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.

Special precautions for safe use in the target species:
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not eat, drink or smoke while handling the veterinary medicinal product. Avoid contact with skin and eyes. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and, if necessary, get medical attention. 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 product or used containers.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only according to benefit-risk assessment by the responsible veterinarian.
Studies performed in laboratory animals showed no teratogenic or embryonic effect of ivermectin at the recommended doses during therapy.

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 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:
None known.

Other precautions:
The veterinary medicinal product has been formulated for use in horses only. Cats, Dogs, especially Collies, Old English Sheepdogs and related breed 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.

7. Adverse events

Horses:
Undetermined frequency (cannot be estimated from the available data):
Oedema (swelling)[1]
Pruritus (itching)[1]

[1]Experienced by some horses carrying heavy infection of *Onchocerca* microfilariae 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

Oral use.
This smaller syringe contains sufficient paste to treat one 600 kg horse, the bigger syringe contains sufficient paste to treat one 800 kg horse at the recommended dose rate (200 mcgs of ivermectin per kg of bodyweight).

Dosing instructions:
Each weight marking on the syringe plunger delivers sufficient paste to treat 100kg of bodyweight. Release the knurled ring by making a ¼ turn and slide the ring up the plunger shaft so that the side of the ring nearest the barrel is at the desired 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 syringe barrel and insert the syringe at the interdental space (the gap between the front and back teeth). Depress the plunger and deposit the paste over the back of the tongue. Immediately raise the horse's head for a few seconds after dosing.
This is a single dose product. Discard after use.

For Best Results: The treatment schedule should be based on the local epidemiological situation. For further advice please consult the veterinary surgeon.

9. Advice on correct administration

To ensure a correct dosage, 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.

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.
This veterinary medicinal product does not require any special storage conditions.
To be used immediately after first opening the oral syringe.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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.

This veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

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

High density polyethylene pre-filled dose-graduated disposable syringe containing 6.42 g (smaller syringe) or 8.56 g (bigger syringe) of product.

Pack sizes:
Cardboard box with 1 oral syringe of 6.42 g.
Cardboard box with 24 oral syringes of 8.56 g.
Cardboard box with 1 oral syringe 6.42 g.
Cardboard box with 24 oral syringes 8.56 g.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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 and manufacturer responsible for batch release:

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