

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON OF 24 SYRINGE BOXES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Horse Oral Paste, 18.7mg/g

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 6.42g Maximec Horse Paste syringe of paste contains 18.7mg/g ivermectin.

3. PHARMACEUTICAL FORM

PRESENTATION

Maximec Horse Oral Paste is a ready-to-administer, 18.7mg/g oral paste formulation of ivermectin.

4. PACKAGE SIZE

Oral syringe application
24 x 6.42g syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

Parasite control for horses, ponies, mares and foals

BROAD SPECTRUM

Maximec Horse Paste kills the adult and larval stages of most of the important internal parasites including small redworms, the arterial stages of the large redworms, lungworms and bots with a single dose.

Maximec Horse Paste kills the small redworms that are resistant to benzimidazole-based wormers.

INDICATIONS

Maximec Horse Paste controls the following horse parasites with one treatment.

Small Redworms: adult and immature stages including strains that are resistant to benzimidazole-based wormers: *Coronocyclus spp.*, *Cyathostomum spp.*, *Cylicocyclus spp.*, *Cylicostephanus spp.*, *Cylicodontophorus bicornatus*, *Gyalocephalus capitatus*, *Parapoteriostomum spp.*, *Petrovinema poculatum.*, *Poteriostomum imparidentatum*.

Large Redworms: adult and arterial larval stages of *Strongylus vulgaris*, adult and tissue larval stages of *S. edentatus*, adults of *S. equinus*, *Craterstomum acuticaudatum* and *Triodontophorus spp.*

Pinworms: adult and immature *Oxyuris equi*.

Lungworms: adult and immature *Dictyocaulus arnfieldi*.
Ascarids: adult and immature *Parascaris equorum*.
Stomach worms: *Trichostrongylus axei* and *Habronema muscae*.
Intestinal threadworms: *Strongyloides westeri*.
Cutaneous worms: microfilariae of *Onchocerca spp.*
Bots: mouth and stomach stages of *Gasterophilus spp*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION

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

Each syringe contains sufficient paste to treat one 600kg horse at the recommended dose rate (200 mcgs of ivermectin per kg of bodyweight).

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.

FOR BEST RESULTS

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 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.

Maximec Horse Paste has a wide safety margin. At the recommended rate Maximec Horse Paste can be used in foals, mares, ponies and horses. Mares may be treated at any stage of pregnancy and the fertility of stallions that have been treated has not been affected.

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD

Horses should not be slaughtered for human consumption within 21 days of treatment. Not permitted for use in lactating mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

SPECIAL PRECAUTIONS FOR USE AND WARNING

Maximec Horse Paste has been formulated specifically for use in horses only. Some horses have experienced reactions involving cutaneous swelling and itching shortly after treatment. In most such cases, the horses have been diagnosed as carrying heavy infections of *Onchocerca microfilariae*, and it is assumed the reactions were the result of microfilariae dying in large numbers. Although the signs have resolved spontaneously in a

few days, symptomatic treatment may be advisable. Consult your Veterinary Surgeon should these signs persist.

Dogs or cats 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.

USER PRECAUTIONS

Do not smoke, drink or eat while handling the product.
Wash hands after use.

10. EXPIRY DATE

EXP: end MM/YY

11. SPECIAL STORAGE CONDITIONS

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

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

ENVIRONMENTAL SAFETY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Dispose of any unused product and empty container in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

(restrictions or conditions regarding supply and use: dependent on territory)

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airtton Close
Tallaght
Dublin 24
Ireland

Distributed by:

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

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4020

17. MANUFACTURER'S BATCH NUMBER

BN:

Logo

DERIVED FROM NATURALLY OCCURRING SUBSTANCES

Ivermectin, the active ingredient of Maximec Horse Paste is produced from a naturally occurring fungus (*Streptomyces avermitilis*).

With Apple Flavour

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1 syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Horse Oral Paste, 18.7mg/g

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 6.42g Maximec Horse Paste syringe of paste contains 18.7mg/g ivermectin.

3. PHARMACEUTICAL FORM

PRESENTATION

Maximec Horse Oral Paste is a ready-to-administer, 18.7 mg/g oral paste formulation

4. PACKAGE SIZE

Oral syringe application 6.42g

5. TARGET SPECIES

Horses

6. INDICATION(S)

Parasite control for horses, ponies, mares and foals

BROAD SPECTRUM

Maximec Horse Paste kills the adult and larval stages of most of the important internal parasites including small redworms, the arterial stages of the large redworms, lungworms and bots with a single dose.

Maximec Horse Paste kills the small redworms that are resistant to benzimidazole-based wormers.

INDICATIONS

Maximec Horse Paste controls the following horse parasites with one treatment.

Small Redworms: adult and immature stages including strains that are resistant to benzimidazole-based wormers: *Coronocyclus spp.*, *Cyathostomum spp.*, *Cylicocyclus spp.*, *Cylicostephanus spp.*, *Cylicodontophorus bicornatus*, *Gyalocephalus capitatus*, *Parapoteriostomum spp.*, *Petrovinema poculatum*, *Poteriostomum imparidentatum*

Large Redworms: adult and arterial larval stages of *Strongylus vulgaris*, adult and tissue larval stages of *S. edentatus*, adults of *S. equinus*, *Craterstomum acuticaudatum* and *Triodontophorus spp.*

Pinworms: adult and immature *Oxyuris equi*.

Lungworms: adult and immature *Dictyocaulus arnfieldi*.

Ascarids: adult and immature *Parascaris equorum*.

Stomach worms: *Trichostrongylus axei* and *Habronema muscae*.

Intestinal threadworms: *Strongyloides westeri*.

Cutaneous worms: microfilariae of *Onchocerca spp.*

Bots: mouth and stomach stages of *Gasterophilus spp.*

Maximec Horse Paste has a wide safety margin. At the recommended rate Maximec Horse Paste can be used in foals, mares, ponies and horses. Mares may be treated at any stage of pregnancy and the fertility of stallions that have been treated has not been affected.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION

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

Each syringe contains sufficient paste to treat one 600kg horse at the recommended dose rate (200 mcg of ivermectin per kg of bodyweight).

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.

FOR BEST RESULTS

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 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.

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD

Horses should not be slaughtered for human consumption within 21 days of treatment.

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

9. SPECIAL WARNING(S), IF NECESSARY

SPECIAL PRECAUTIONS FOR USE AND WARNINGS

Maximec Horse Paste has been formulated specifically for use in horses only. Some horses have experienced reactions involving cutaneous swelling and itching shortly after treatment. In most such cases, the horses have been diagnosed as carrying heavy infections of *Onchocerca microfilariae*, and it is assumed the reactions were the result of microfilariae dying in large numbers. Although the signs have resolved spontaneously in a few days, symptomatic treatment may be advisable. Consult your Veterinary Surgeon should these signs persist.

Dogs or cats 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.

USER PRECAUTIONS

Do not smoke, drink or eat while handling the product.
Wash hands after use.

10. EXPIRY DATE

Expiry: end MM/YY

11. SPECIAL STORAGE CONDITIONS

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

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

ENVIRONMENTAL SAFETY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Dispose of any unused product and empty container in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

(restrictions or conditions regarding supply and use: dependent on territory)

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

Distributed by:

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

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4020

17. MANUFACTURER'S BATCH NUMBER

BN

Bar Code

Logo

DERIVED FROM NATURALLY OCCURRING SUBSTANCES

Ivermectin, the active ingredient of Maximec Horse Paste is produced from a naturally occurring fungus (*Streptomyces avermitilis*).

With Apple Flavour

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Horse Oral Paste, 18.7mg/g

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 18.7 mg/g Ivermectin as active. Read package insert before use.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Syringe application 6.42grams

4. ROUTE(S) OF ADMINISTRATION

Oral

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

Expiry: end MM/YY

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
Keep out of reach and sight of children.

(restrictions or conditions regarding supply and use: dependent on territory)

LOGO

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

Parasite control for horses.

With Apple Flavour

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Maximec Horse Oral Paste, 18.7mg/g

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

LU/NL/UK:

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

Site responsible for batch release

Bimeda Animal Health Limited
Unit 2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

Distributed By:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Horse Oral Paste, 18.7mg/g

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

Maximec Horse Paste is ready-to-administer, 18.7mg/g oral paste formulation of ivermectin with apple flavour.

4. INDICATION(S)

For broad spectrum use in parasite control for horses, ponies, mares and foals. Maximec Horse Paste kills the adult and larval stages of most of the important internal parasites including small redworms, the arterial stages of the large redworms, lungworms

and bots with a single dose. Maximec Horse Paste kills the small redworms that are resistant to benzimidazole-based wormers.

Maximec Horse Paste has a wide safety margin. At the recommended rate Maximec Horse Paste can be used in foals, mares, ponies and horses. Mares may be treated at any stage of pregnancy and the fertility of stallions that have been treated has not been affected.

Maximec Horse Paste controls the following horse parasites with one treatment:

Large Redworms: adult and arterial larval stages of *Strongylus vulgaris*, adult and tissue larval stages of *S. edentatus*, adults of *S. equinus*, *Craterstonum acuticaudatum* and *Triodontophorus spp.*

Small Redworms: adult and immature stages including strains that are resistant to benzimidazole-based wormers; *Coronocyclus spp.*, *Cyathostomum spp.*, *Cylicocyclus spp.*, *Cylicostephanus spp.*, *Cylicodontophorus bicornatus*, *Gyalocephalus capitatus*, *Parapoteriostomum spp.*, *Petrovinema poculatum*, *Poteriostomum imparidentatum*.

Pinworms: adult and immature *Oxyuris equi*.

Lungworms: adult and immature *Dictyocaulus arnfieldi*.

Ascarids: adult and immature *Parascaris equorum*.

Stomach worms: *Trichostrongylus axei* and *Habronema muscae*.

Intestinal threadworms: *Strongyloides westeri*.

Cutaneous worms: microfilariae of *Onchocerca spp.*

Bots: mouth and stomach stages of *Gasterophilus spp.*

5. CONTRAINDICATIONS

Maximec Horse Paste has been formulated specifically for use in horses only. Dogs or cats 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.

6. ADVERSE REACTIONS

Some horses have experienced reactions involving cutaneous swelling and itching shortly after treatment. In most such cases, the horses have been diagnosed as carrying heavy infections of *Onchocerca microfilariae*, and it is assumed the reactions were the result of microfilariae dying in large numbers. Although the signs have resolved spontaneously in a few days, symptomatic treatment may be advisable. Consult your Veterinary Surgeon should these signs persist.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses

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

Each syringe contains sufficient paste to treat one 600kg horse at the recommended dose rate (200 mcgs of ivermectin per kg of bodyweight).

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

For Best Results: 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 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 PERIOD

Horses should not be slaughtered for human consumption within 21 days of treatment. Not permitted for use in lactating mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

For animal treatment only.

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

12. SPECIAL WARNING(S)

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.

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

User Warnings

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

Wash hands after use.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container. Dispose of any unused product and empty container in accordance with guidance from your local waste regulation authority

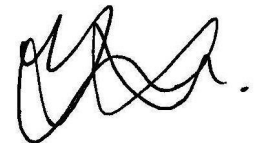
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

(restrictions or conditions regarding supply and use: dependent on territory)

DERIVED FROM NATURALLY OCCURRING SUBSTANCES

Ivermectin, the active ingredient of Maximec Horse Paste is produced from a naturally occurring fungus (*Streptomyces avermitilis*).

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 23 August 2019