LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box for 10 syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equest Pramox 19.5 mg/g + 121.7 mg/g oral gel

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substances

Moxidectin	19.5 mg
Praziquantel	121.7 mg

Excipients

Benzyl alcohol (E1519)	220.0 mg
Butylhydroxytoluene (E321)	0.8 mg

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

Box of 10 syringes containing 14.4 g of gel

5. TARGET SPECIES

Horses

6. INDICATION(S)

For the treatment of mixed infestations cause by moxidectin sensitive strains of nematodes or arthropods and praziquantel sensitive strains of cestodes.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

A single syringe treats a 700 kg horse.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 64 days.
Milk: not permitted for use in lactating mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
<Once broached,/opened, use by…>

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product. The product is toxic for fish and aquatic organisms.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4058

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box for 20 syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equest Pramox 19.5 mg/g + 121.7 mg/g oral gel

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substances

Moxidectin	19.5 mg
Praziquantel	121.7 mg

Excipients

Benzyl alcohol (E1519)	220.0 mg
Butylhydroxytoluene (E321)	0.8 mg

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

Box of 20 syringes containing 14.4 g of gel

5. TARGET SPECIES

Horses

6. INDICATION(S)

For the treatment of mixed infestations cause by moxidectin sensitive strains of nematodes or arthropods and praziquantel sensitive strains of cestodes.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

A single syringe treats a 700 kg horse.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 64 days.
Milk: not permitted for use in lactating mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
<Once broached,/opened, use by…>

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product. The product is toxic for fish and aquatic organisms.

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4058

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box for 1 syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equest Pramox 19.5 mg/g + 121.7 mg/g oral gel

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substances

Moxidectin	19.5 mg
Praziquantel	121.7 mg

Excipients

Benzyl alcohol (E1519)	220.0 mg
Butylhydroxytoluene (E321)	0.8 mg

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

Box of 1 syringe containing 14.4 g of gel

5. TARGET SPECIES

Horses

6. INDICATION(S)

For the treatment of mixed infestations cause by moxidectin sensitive strains of nematodes or arthropods and praziquantel sensitive strains of cestodes.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

A single syringe treats a 700 kg horse.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 64 days.
Milk: not permitted for use in lactating mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
<Once broached,/opened, use by…>

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

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

Any unused veterinary medicinal products or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. The product is toxic for fish and aquatic organisms. Do not contaminate ponds, waterways, or ditches with the product or used syringes.

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4058

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

14.4 g syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equest Pramox 19.5 mg/g + 121.7 mg/g oral gel

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Moxidectin 19.5 mg/g + Praziquantel 121.7 mg/g

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

14.4g syringe

4. ROUTE(S) OF ADMINISTRATION

Oral

5. WITHDRAWAL PERIOD(S)

Meat and offal: 64 days.
Milk: not permitted for use in lactating mares producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached,/opened, use by…….

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Equest Pramox 19.5 mg/g + 121.7 mg/g oral gel

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

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer for the batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equest Pramox 19.5 mg/g + 121.7 mg/g oral gel

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

Each g contains:

Active substances

Moxidectin	19.5 mg
Praziquantel	121.7 mg

Excipients

Benzyl alcohol (E1519)	220.0 mg
Butylhydroxytoluene (E321)	0.8 mg

4. INDICATION(S)

In horses:
Equest Pramox Oral Gel is a parasiticide active against a wide range of internal and external parasites of horses, ponies, mares and foals. It contains moxidectin, a second generation macrocyclic lactone of the milbemycin family. Moxidectin paralyses and kills parasites by its effect on their nervous systems. It also contains praziquantel, a parasiticide widely used in many species for the specific control of

tapeworm. Praziquantel is quickly absorbed via the tegument of the tapeworm and distributed evenly within the parasite. It disrupts the metabolism of the tapeworm, resulting in contraction and paralysis of the parasite.

The veterinary medicinal product is indicated for treatment of mixed cestodes and nematodes or arthropods infections, caused by moxidectin and praziquantel sensitive strains of:

– Large strongyles:
. *Strongylus vulgaris* (adult stages)
. *Strongylus edentatus* (adult stages)
. *Triodontophorus brevicauda* (adults)
. *Triodontophorus serratus* (adults)
. *Triodontophorus tenuicollis* (adults)

– Small strongyles (adults and intraluminal larval stages):
. *Cyathostomum* spp
. *Cylicocyclus* spp
. *Cylicostephanus* spp
. *Cylicodontophorus* spp
. *Gyalocephalus* spp

– Ascarids:
. *Parascaris equorum* (adults)

– Other species:
. *Oxyuris equi* (adult stages)
. *Habronema muscae* (adults)
. *Gasterophilus intestinalis* (L2, L3)
. *Gasterophilus nasalis* (L2, L3)
. *Strongyloides westeri* (adults)
. *Trichostrongylus axei (*adult stages*)*

– Tapeworm (adults):
. *Anoplocephala perfoliata*
. *Anoplocephala magna*
. *Paranoplocephala mammillana*

The egg reappearance period of small strongyles is 90 days.
The product is effective against (developing) intramucosal L4 stages of small strongyles. At 8 weeks after treatment, early (hypobiotic) EL3 stages of small strongyles are eliminated.

The veterinary medicinal product has been shown to be safe for use in breeding, pregnant and lactating mares. The administration of the product does not adversely affect the fertility of the mares.

5. CONTRAINDICATIONS

Do not administer to young foals less than 6.5 months old

Do not use in case of hypersensitivity to the active substance or to any of the excipients
The product has been formulated specifically for use in horses only. Dogs and cats may be adversely affected by the concentration of moxidectin in this product if they are allowed to ingest spilled gel or have access to used syringes.

6. ADVERSE REACTIONS

Mouth pain, flaccid lower lip, swelling of the muzzle, hypersalivation and anorexia have been observed in rare cases. Ataxia has been reported on rare occasions, lethargy and tremor in very rare cases. These adverse effects are transient and disappear spontaneously.
Digestive discomfort (colic, loose stool) has been observed in very rare cases based on post-marketing surveillance data.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses

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

A single oral dose of 400 µg moxidectin/kg bodyweight and 2.5 mg praziquantel/kg bodyweight using the calibrated syringe of one gradation per 25 kg live weight.
To ensure administration of a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing should be checked.
Use of a scale or weight tape is recommended to ensure accurate dosing.

Before the first dose, hold the syringe with the capped end pointing to the left and so that you can see the weight measurements and tick marks (small black lines). Set the syringe to zero by moving the dial ring so the left side is set at the first full black mark and depress the plunger, safely discarding any paste that is expelled.

To dose the product, hold the syringe as previously described. Each tick mark relates to 25 kg of body weight and to 10mg moxidectin/62.5 mg praziquantel. Turn the dial ring until the left side of the ring lines up with the weight of the animal.

A single syringe treats a 700 kg horse.

In the case of cestode treatment the dose of praziquantel in the product has been selected to the top end of the dosing range.
Veterinary advice should be given on appropriate dosing programmes and stock management to achieve optimum parasite control.

9. ADVICE ON CORRECT ADMINISTRATION

To avoid overdosing, care should be taken to accurately dose foals, especially low body weight foals or pony foals.
Do not use the same syringe to treat more than one animal unless horses are running together or in direct contact with each other in the same premises.

In order to limit the impact of moxidectin on dung fauna, and due to insufficient data regarding environmental risk of praziquantel, horses should not be turned out onto pasture within 3 days of treatment. For optimum control of bots, the product should be administered in the autumn, after the end of the fly season and before spring as the larvae may start to pupate and therefore are less sensitive to treatment.

Parasite resistance to a particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. The veterinarian should give advice regarding appropriate dosing programmes and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations.

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;
- Under-dosing which may due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (If any).
- 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.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 64 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. Do not store above 25 °C.
Do not use after the expiry date stated on the carton after “EXP”.
Shelf-life after first opening the container: 6 months.

12. SPECIAL WARNING(S)

This product may cause eye irritation, skin irritation and skin sensitisation.
Avoid contact with skin and eyes.
Use protective gloves.
Wash hands or any exposed area after use.
Do not smoke, drink or eat while handling the product.
In the event of eye contact flush the eye with copious amount of clean water and seek medical advice.
In case of accidental ingestion, seek medical help and show the doctor the package insert.

Overdose (symptoms, emergency procedure, antidotes if necessary)

Transient adverse reactions may occur at the recommended treatment dose in foals. In adults transient adverse reactions may occur at 3 times the recommended dose. The symptoms are depression, inappetence, ataxia, flaccid lower lip in the 8 to 24 hours following treatment. Symptomatic treatment is not generally necessary and recovery is generally complete within 24 to 72 hours. There is no specific antidote.

Other precautions regarding impact on the environment

Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance; therefore, exposure of the environment to moxidectin must be limited to the extent possible. Treatments should be administered only when necessary and should be based on faecal egg counts or evaluation of the risk of infestation at the animal and/or herd level. In order to reduce the emission of moxidectin to surface water and based on the excretion profile of moxidectin when administered as the oral formulation to horses, treated animals should not have access to watercourses during the first week after treatment.

Like other macrocyclic lactones, moxidectin has the potential to adversely affect non-target organisms, in particular aquatic organisms and dung fauna.

- Faeces containing moxidectin excreted onto pasture by treated animals may temporarily reduce the abundance of dung feeding organisms. Following treatment of horses with the product, levels of moxidectin that are potentially toxic to dung beetles and flies may be excreted over a period of more than 1 week and may decrease dung fauna abundance.
- Moxidectin is inherently toxic to aquatic organisms including fish. The product should be used only according to the label instructions.

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

Any unused veterinary medicinal products or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product. The product is toxic for fish and aquatic organisms.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2023

15. OTHER INFORMATION

High density polyethylene syringe containing 14.4 g of gel with a graduated plunger with a low density polyethylene piston and cap packed as follows:

- Box containing one syringe.
- Box containing 10 individually boxed syringes.
- Box containing 20 individually boxed syringes.
- Box containing 20 syringes.

Not all pack sizes may be marketed.

Approved 19 December 2023