

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box for 1, 10 or 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

**3. PACKAGE SIZE**

Box of 1 syringe containing 14.4 g of gel  
Box of 10 syringes containing 14.4 g of gel  
Box of 20 syringes containing 14.4 g of gel

**4. TARGET SPECIES**

Horses.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Oral use.

**7. WITHDRAWAL PERIODS**

Withdrawal period:  
Meat and offal: 64 days.  
Milk: not permitted for use in animals producing milk for human consumption.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use by...  
Once opened use within 6 months.

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C.

**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**

Zoetis UK Limited

**14. MARKETING AUTHORISATION NUMBER**

Vm 42058/3041

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Single dose syringe

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Equest Pramox



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Moxidectin 19.5 mg/g + Praziquantel 121.7 mg/g

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use by.....

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

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

### 2. Composition

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

Pale yellow to orange/pink oral gel.

### 3. Target species

Horses.

### 4. Indications for use

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 paralyzes 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 veterinary medicinal 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 veterinary medicinal 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 cases of hypersensitivity to the active substance or to any of the excipients.

The veterinary medicinal product has been formulated specifically for use in horses only. Dogs and cats may be adversely affected by the concentration of moxidectin in this veterinary medicinal product if they are allowed to ingest spilled gel 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 body weight, misadministration of the veterinary medicinal 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.

For optimum control of bots, the veterinary medicinal 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.

Special precautions for safe use in the target species:

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.

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

This veterinary medicinal product may cause eye irritation, skin irritation and skin sensitisation.

Avoid contact with skin and eyes.

Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product.

Wash hands or any exposed area after use.

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

In case of eye contact, flush the eye with copious amounts of clean water and seek medical advice immediately and show the package leaflet or the label to the physician. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of 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 veterinary medicinal 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 veterinary medicinal product should be used only according to the label instructions.

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.

#### Pregnancy and lactation:

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.

#### Interaction with other medicinal products and other forms of interaction:

The effects of GABA agonists are increased by moxidectin.

#### Overdose:

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.

## **7. Adverse events**

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersalivation <sup>1</sup> , Mouth pain <sup>1</sup> Swollen muzzle <sup>1</sup> Ataxia (incoordination) <sup>1</sup> , Droopy lower lip <sup>1</sup> Anorexia <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder (e.g. colic, loose stool) Tremor <sup>1</sup> Lethargy <sup>1</sup>

<sup>1</sup> These adverse effects are transient and disappear spontaneously.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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: {national system details}.

## **8. Dosage for each species, routes and method of administration**

Oral use.

A single oral dose of 400 µg moxidectin/kg body weight and 2.5 mg praziquantel/kg body weight using the calibrated syringe of one gradation per 25 kg live weight. A single syringe treats a 700 kg horse.

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.

## **9. Advice on correct administration**

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 10 mg moxidectin/62.5 mg praziquantel. Turn the dial ring until the left side of the ring lines up with the weight of the animal.

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.

## **10. Withdrawal periods**

Meat and offal: 64 days.

Milk: Not authorised for use in animals 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 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. The veterinary medicinal product should not enter water courses as moxidectin may be dangerous for fish and other aquatic organisms. These measures should help to protect the environment. 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**

Vm 42058/3041

High density polyethylene syringe containing 14.4 g of gel with a graduated polypropylene 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.

### **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](http://www.gov.uk).

### **16. Contact details**

#### **Marketing authorisation holder:**

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

**Manufacturer responsible for the batch release:**

Zoetis Manufacturing & Research Spain, S.L.  
Ctra. Camprodón s/n "la Riba"  
17813 Vall de Bianya  
Girona  
Spain

**17. Other information**

*To be completed nationally*

*Gavin Hall*  
Approved: 30 December 2024