1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances
Moxidectin 19.5 mg
Praziquantel 121.7 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	220.0 mg
Butylhydroxytoluene (E321)	0.8 mg
Anhydrous colloidal silica	
Ethanol, anhydrous	
Polysorbate 80	
Ethyl cellulose	
Propylene glycol dicaprylate/dicaprate	

Pale yellow to orange/pink oral gel.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the 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.

3.3 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.

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 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.

3.5 Special precautions for use

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:

- 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.

3.6 Adverse events

Horses:

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

[1] These adverse effects are transient and disappear spontaneously.

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 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.

3.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by moxidectin.

3.9 Administration routes and dosage

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.

Dosing instructions:
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 veterinary medicinal 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 veterinary medicinal 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.

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

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.

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: 64 days.
Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP 54 AB 52

4.2 Pharmacodynamics

Moxidectin is a parasiticide active against a wide range of internal and external parasites and is a second-generation macrocyclic lactone of the milbemycin family. Moxidectin interacts with GABA receptors and chloride channels. The net effect is to open the chloride channels on the postsynaptic junction to allow the inflow of chloride ions and induce an irreversible resting state. This results in flaccid paralysis and eventual death of parasites exposed to the drug.
Praziquantel is a parasiticide widely used in many species as an anthelmintic.
Praziquantel is quickly absorbed via the tegument of the parasite and distributed. *In vitro* and *in vivo* important lesions of the tegument of the parasite are seen that provoke contraction and paralysis of the parasite. Praziquantel modifies the permeability of the parasitic membrane to calcium ions, which disrupts the metabolism of the parasite.
The veterinary medicinal product is effective against benzimidazole resistant strains of cyathostomes.

4.3 Pharmacokinetics

Moxidectin is absorbed orally and maximum blood concentration is achieved approximately 6 to 8 hours after administration.
The drug is distributed throughout the body tissues but due to its lipophilicity it is selectively concentrated in the fat.
The elimination half-life is 11days.
Moxidectin undergoes partial biotransformation by hydroxylation in the body and the only significant route of excretion is the faeces.
Praziquantel is quickly and almost totally absorbed in the body, rapidly distributed to all organs, half life elimination is less than 1 hour in horses. Praziquantel is rapidly metabolised in the liver. Its principal metabolite is a related 4-hydroxycyclohexyl component.

Environmental properties

Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance. In particular, in acute and chronic toxicity studies with algae, crustaceans and fish, moxidectin showed toxicity to these organisms, yielding the following endpoints:

Organism		EC50	NOEC
Algae	*S. capricornutum*	>86.9 µg/l	86.9 µg/l
Crustaceans (Water fleas)	*Daphnia magna* (acute)	0.0302 µg/l	0.011 µg/l
	Daphnia magna (reproduction)	0.0031 µg/l	0.010 µg/l
Fish	*O. mykiss*	0.160 µg/l	Not determined
	L. macrochirus	0.620 µg/l	0.52 µg/l
	P. promelas (early life stages)	Not applicable	0.0032 µg/l
	Cyprinus carpio	0.11 µg/l	Not determined

EC_{50}: the concentration which results in 50 % of the test species individuals being adversely affected, i.e. both mortality and sub-lethal effects.
NOEC: the concentration in the study at which no effects are observed.

This implies that when allowing moxidectin to enter water bodies, this may have a severe and lasting impact on aquatic life. To mitigate this risk, all precautions for use and disposal must be adhered to.

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.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

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.

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 moxidectin may be dangerous for fish and other aquatic organisms.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/026/001

8. DATE OF FIRST AUTHORISATION

09 December 2013

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

24 July 2024

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).