1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE 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

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Gel.
Pale yellow to orange/pink oral gel.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for Use, specifying the target species

In horses:
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 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.

4.3 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.

4.4 Special warnings for each target species

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.

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.

4.5 Special Precautions for Use

Special precautions for use in animals

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 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.

Other precautions

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.

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:

- 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.

4.6 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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by moxidectin.

4.9 Amount to be administered and administration route

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.

4.10 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.

4.11 Withdrawal period

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

5. PHARMACOLOGICAL PROPERTIES

Therapeutic group: antiparasitic product, endectocide

ATCVet code : QP 54 AB 52, moxidectin combination

5.1 Pharmacodynamic properties

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 product is effective against benzimidazole resistant strains of cyathostomes.

5.2 Pharmacokinetic particulars

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.

5.3 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		**EC_{50}**	**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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Butyl hydroxytoluene (E321)
Anhydrous colloidal silica

Ethanol, anhydrous
Polysorbate 80
Ethyl cellulose
Propylene glycol dicaprylate/dicaprate

6.2 Major incompatibilities

None known.

6.3 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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

HDPE syringe containing 14.4 g of gel with graduated polypropylene plunger and LDPE 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 size may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.,

8. MARKETING AUTHORISATION NUMBER

VPA10387/026/001

9. DATE OF RENEWAL OF AUTHORISATION

09/12/2013

10. DATE OF REVISION OF THE TEXT

11/09/2023