

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Names used:

EQUEST PRAMOX ORAL GEL in all the countries except

Germany: EQUEST PRAMOX 19.5 mg/g + 121.7 mg/g Gel zum eingeben

Spain: EQUEST PRA-MOX

Portugal and Poland: EQUEST PRAMOX 19.5 mg/g + 121.7 mg/g oral gel

Denmark: Equest Pramox

Sweden: Cydectin Comp Vet.

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.

See also section 4.7

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

i. 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.

ii. 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.

a. 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.

4.6 Adverse reactions

Flaccid lower lip, ataxia and swelling of the muzzle could be observed on rare occasions in young animals. These adverse effects are transient and disappear spontaneously.

In case of very high worm burdens, destruction of the parasites may cause a mild transient colic and loose faeces in the treated horse.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation in 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. Hold the syringe with the capped end pointing to the left so that you can see the weight measurements and tick marks (small black lines). Each tick mark relates to 25 kg of bodyweight. Turn the dial ring until the left side of the ring lines up with the weight of the animal. A single syringe treats a 575 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 11 days.

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.

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 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life of the veterinary medicinal product after the first opening: 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 11.8 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

The product is toxic for fish and aquatic organisms.

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 ponds, waterways, or ditches with the product or used syringes.

7. MARKETING AUTHORISATION HOLDER

Pfizer Ltd
Ramsgate Road
Sandwich
Kent
CT13 9NJ

8. MARKETING AUTHORISATION NUMBER

Vm 00057/4344

9. DATE OF RENEWAL OF AUTHORISATION

27 May 2010

10. DATE OF REVISION OF THE TEXT

November 2010