Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUEST ORAL GEL, 18.92 mg/g, oral gel for horses and ponies

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance	
Moxidectin	18.92 mg
Excipients qsp	
Benzyl Alcohol (E1519)	37.84 mg
Disodium Edetate	0.24 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Gel
Yellow gel.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses and ponies

4.2 Indications for use, specifying the target species

The veterinary medicinal product is indicated for treatment of infections caused by moxidectin sensitive strains of:

Large strongyles:
Strongylus vulgaris (adults and arterial stages)
Strongylus edentatus (adults and visceral 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 (adult and larval stages)

Other species:
Oxyuris equi (adult and larval stages)
Habronema muscae (adults)

Gasterophilus intestinalis (L2, L3)
Gasterophilus nasalis (L2, L3)
Strongyloides westeri (adults)
Trichostrongylus axei

The veterinary medicinal product has a persistent efficacy of two weeks against small strongyles. The excretion of small strongyles eggs is suppressed for 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.

4.3 Contraindications

Do not administer to young foals less than 4 months.
Do not administer in case of known hypersensitivity to the active ingredient or to any other milbemycins and to any other ingredients of the veterinary medicinal product.

4.4 Special warnings for each target species

None

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. Equest has been formulated specifically for use in horses only. Dogs or cats may be adversely affected by the concentration of moxidectin in this veterinary medicinal product if they are allowed to ingest spilled paste or have access to used syringes. Neurological signs (such as ataxia, muscle tremor and convulsions) and digestive clinical signs (such as hypersalivation) were recorded.

Special precautions to be taken by the person administering the product to the animals

Avoid direct contact with skin and eyes.
The use of protective gloves is recommended.
Wash hands or any exposed area after use.
Do not smoke, drink or eat while handling the veterinary medicinal product.
In the event of eye contact, flush the eye with copious amounts of clean water and seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

Ataxia, depression, abdominal pain, muscle tremor**,** flaccid lower lip and swelling of the muzzle could be observed on very rare occasions These adverse effects are usually transient and disappear spontaneously in most cases.

4.7 Use during pregnancy, lactation or lay

The veterinary medicinal product has been shown to be safe for use in pregnant and lactating mares.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

A single oral dose of 400 µg moxidectin/kg bodyweight using the calibrated syringe. 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). Each tick mark relates to 25 kg of body weight. Turn the dial ring until the left side of the ring lines up with the weight of the animal.

Use of a scale or weight tape is recommended to ensure accurate dosing.

A single syringe treats a 700 kg horse.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Adverse reactions may occur at 2 times the recommended dose in foals and 3 times the recommended dose in adults. The symptoms are depression, inappetance, ataxia and flaccid lower lip in the 8 to 24 hours following treatment.Symptoms of moxidectin overdose are the same as those observed in very rare occasions at the recommended dosage. In addition, hypothermia and lack of appetite may occur . There is no specific antidote.

4.11 Withdrawal Period(s)

Meat and offal : 32 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides (milbemycins)
ATC Vet code : QP54AB02

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 and glutamate gated 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.

The veterinary medicinal product is effective against benzimidazole resistant strains of cyathostomes.

5.2 Pharmacokinetic properties

Moxidectin is absorbed following oral administration with maximum blood concentrations being achieved 8 hours post application.
Bioavailability by the oral route is 40%. 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 28 days.
Moxidectin undergoes partial biotransformation by hydroxylation in the body and the only significant route of excretion is the faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Disodium edetate
Poloxamer 407
Simethicone
Sodium phosphate dibasic
Sodium dihydrogen phosphate
Propylene glycol
Polysorbate 80
Water

6.2 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

Store below 25°C.

6.5 Nature and composition of immediate packaging

High density polyethylene syringe containing 14.8 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 syringes.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

The veterinary medicinal product is toxic for fish and aquatic organisms.
Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or used syringes.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland,
Trading as Pfizer Animal Health,
Ringaskiddy,
Co. Cork,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/151/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th February 2008

10 DATE OF REVISION OF THE TEXT

June 2013