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:

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)	37.84 mg
Disodium Edetate	0.24 mg
Butylhydroxytoluene	0.114 mg
Poloxamer 407	
Simethicone	
Disodium phosphate dodecahydrate	
Sodium dihydrogen phosphate dihydrate	
Propylene glycol	
Polysorbate 80	
Water	

Yellow oral gel.

3. CLINICAL INFORMATION

3.1 Target species

Horses and ponies.

3.2 Indications for use for each 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.

3.3 Contraindications

Do not administer to young foals less than 4 months.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients or other milbemycins.

3.4 Special warnings

None.

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 bodyweight 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. The veterinary medicinal product has been formulated specifically for use in horses only.

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

Avoid direct 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.

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 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.

Other precautions:

The veterinary medicinal product 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.

3.6 Adverse events

Horses and ponies:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Abdominal pain[1] Swollen muzzle[1] Ataxia[1], muscle tremor[1], droopy lower lip[1] Depression[1]

[1] In young animals. These adverse effects are usually transient and disappear spontaneously in most cases.

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 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 pregnant and lactating mares.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
Single administration of 400 µg moxidectin/kg bodyweight using the calibrated syringe.
Each syringe treats a 700 kg horse.

Bodyweight and dosage should be accurately determined prior to treatment. Underdosing could result in ineffective use and may favour resistance development. 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 product, hold the syringe as previously described. Each tick mark relates to 25 kg of bodyweight and to 10 mg moxidectin. Turn the dial ring until the left side of the ring lines up with the weight of the animal.

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

Adverse reactions may occur at 2 times the recommended dose in foals and 3 times the recommended dose in adults. The symptoms are depression, inappetence, 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.

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: 32 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AB02

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 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.

4.3 Pharmacokinetics

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.

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

Store below 25 °C.

5.4 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.

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

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as moxidectin may be dangerous for fish and other aquatic organisms.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBERS

Vm 42058/5142
Vm 42058/3035

8. DATE OF FIRST AUTHORISATION

15 January 1999

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

August 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 18 February 2025