SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimoxectin 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:
Benzyl Alcohol (E1519) 37.84 mg
Disodium Edetate 0.24 mg

For the 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 use in cases of hypersensitivity to the active substance or to any of the excipients.

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. The 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.

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

The product may cause eye and skin irritation.
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.

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 (frequency and seriousness)

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

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 pregnant and lactating mares.

4.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by moxidectin.

4.9 Amounts to be administered and administration route

A single oral dose of 400 µg moxidectin/kg bodyweight using the calibrated syringe.

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. 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 periods

Meat and offal: 32 days
Milk: not permitted for use in lactating mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides (milbemycins)

ATCvet 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.

Moxidectin 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.

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		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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Disodium edetate
Poloxamer 407
Simeticone
Disodium phosphate dodecahydrate
Sodium dihydrogenphosphate dihydrate
Propylene glycol
Polysorbate 80
Water for injections.

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

Store below 25°C

6.5 Nature and content 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 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 UK Limited
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8. MARKETING AUTHORISATION NUMBER

Vm 42058/4207

9. DATE OF FIRST AUTHORISATION

28 March 2014

10. DATE OF REVISION OF THE TEXT

December 2019

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