PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equest Oral Gel 18.92 mg/g Oral Gel.

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substance
Moxidectin 18.92 mg

3. PACKAGE SIZE

Box of 1 syringe containing 14.8 g of gel
Box of 10 syringes containing 14.8 g of gel
Box of 20 syringes containing 14.8 g of gel

4. TARGET SPECIES

Horses and ponies.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 32 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached/opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5142
Vm 42058/3035

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equest Oral Gel.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Moxidectin 18.92 mg/g
14.8 g syringe

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached/opened use by…

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equest Oral Gel 18.92 mg/g Oral Gel for horses and ponies.

2. Composition

Each gram contains:

Active substance

Moxidectin	18.92 mg

Excipients

Benzyl alcohol	37.84 mg
Disodium edetate	0.24 mg
Butylhydroxytoluene	0.114 mg

Yellow oral gel.

3. Target species

Horses and ponies.

4. Indications for use

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 strongyle 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.

5. Contraindications

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

6. Special warnings

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. 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:
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, in particular aquatic organisms and dung fauna.

- 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.

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

Overdose:
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.

7. Adverse events

Horses and ponies.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Abdominal pain[1] Swollen muzzle[1] Ataxia (incoordination)[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. If you notice any side effects, even those not already

listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

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.

10. Withdrawal periods

Meat and offal: 32 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after “Exp.”.
Shelf-life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
This 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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5142
Vm 42058/3035

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
Spain

17. Other information

POM-VPS

Gavin Hall
Approved: 18 February 2025