PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box for 10 syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimoxectin 18.92 mg/g Oral Gel for Horses and Ponies.
Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance	**mg/g**
Moxidectin	18.92
Excipients	
Benzyl alcohol	37.84
Disodium edetate	0.24

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

Box of 10 syringes containing 14.8 g of gel

5. TARGET SPECIES

Horses and ponies

6. INDICATIONS

For OTC products

For the treatment of infections caused by moxidectin sensitive strains of nematodes (roundworms) and bots in horses.

7. METHOD AND ROUTES OF ADMINISTRATION

A single oral dose of 400µg 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.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

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

9. SPECIAL WARNINGS, IF NECESSARY

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 6 months

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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 veterinary medicinal product is toxic for fish and aquatic organisms.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

Only for those countries where the product is available subject to prescription.
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4207

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box for 20 syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimoxectin 18.92 mg/g Oral Gel for Horses and Ponies.
Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance	**mg/g**
Moxidectin	18.92
Excipients	
Benzyl alcohol	37.84
Disodium edetate	0.24

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

Box of 20 syringes containing 14.8 g of gel

5. TARGET SPECIES

Horses and ponies

6. INDICATIONS

For OTC products

For the treatment of infections caused by moxidectin sensitive strains of nematodes (roundworms) and bots in horses.

7. METHOD AND ROUTES OF ADMINISTRATION

A single oral dose of 400µg 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.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

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

9. SPECIAL WARNINGS, IF NECESSARY

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 6 months

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.
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 veterinary medicinal product is toxic for fish and aquatic organisms.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

Only for those countries where the product is available subject to prescription.
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4207

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box for 1 syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimoxectin 18.92 mg/g Oral Gel for Horses and Ponies.
Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance	**mg/g**
Moxidectin	18.92
Excipients	
Benzyl alcohol	37.84
Disodium edetate	0.24

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

Box of 1 syringe containing 14.8 g of gel

5. TARGET SPECIES

Horses and ponies

6. INDICATIONS

For OTC products

For the treatment of infections caused by moxidectin sensitive strains of nematodes (roundworms) and bots in horses.

7. METHOD AND ROUTES OF ADMINISTRATION

A single oral dose of 400µg 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.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

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

9. SPECIAL WARNINGS, IF NECESSARY

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 6 months
Once broached,/opened, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.
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 veterinary medicinal product is toxic for fish and aquatic organisms.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

Only for those countries where the product is available subject to prescription.
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4207

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

14.8 g syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimoxectin 18.92 mg/g Oral Gel for Horses and Ponies.
Moxidectin

2. QUANTITY OF THE ACTIVE SUBSTANCE

Moxidectin 18.92 mg/g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

14.8g syringe

4. ROUTE(S) OF ADMINISTRATION

Oral

5. WITHDRAWAL PERIODS

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

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 6 months
Once broached,/opened, use by…….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET
Equimoxectin 18.92 mg/g Oral Gel for Horses and Ponies.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer for the batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera Camprodon s/n – La Riba
17813 – Vall de Bianya
Girona,
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equimoxectin 18.92 mg/g Oral Gel for Horses and Ponies.
Moxidectin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance	**mg/g**
Moxidectin	18.92
Excipients	
Benzyl alcohol	37.84
Disodium edetate	0.24

Yellow gel.

4. INDICATIONS

In horses and ponies:
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.

6. ADVERSE REACTIONS

Ataxia (incoordination), depression, abdominal pain, muscle tremor, flaccid (weak) 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.

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses and ponies

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

A single oral dose of 400µg 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.

9. ADVICE ON CORRECT ADMINISTRATION

To avoid overdosing, care should be taken to accurately dose foals, especially in 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/incoordination, muscle tremor and convulsions) and digestive clinical signs such as hypersalivation (increased salivation) were recorded.

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.

10. WITHDRAWAL PERIODS

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and syringe label after “EXP” The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 6 months.

12. SPECIAL WARNINGS

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.

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 (incoordination) and flaccid (weak) 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.

Interaction with other medicinal products and other forms of interaction:
The effects of GABA agonists are increased by moxidectin.

Pregnancy and lactation:
Mares may be treated at any stage of pregnancy and lactation.

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, 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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 veterinary medicinal product is toxic for fish and aquatic organisms.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Approved 03 December 2019