ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Container of 10 syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substance:
Moxidectin 18.92 mg

Excipients qsp:
Benzyl Alcohol (E1519) 37.84 mg
Butylhydroxytoluene 0.114 mg

3. PHARMACEUTICAL FORM

Oral gel.
Pale yellow to yellow, clear gel.

4. PACKAGE SIZE

10 x 14.8g.

5. TARGET SPECIES

Horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use. A single dose of 400µg moxidectin/kg bodyweight should be administered orally using the calibrated syringe. Before the first dose, hold the syringe with the capped end pointing to the left so that the weight measurements and tick marks (small black lines) can be seen. Set the syringe to zero by moving the dial ring so that 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 veterinary medicinal product, hold the syringe as previously described. 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. The accuracy of the dosing device should be thoroughly checked.

To ensure a correct dosage, the body weight should be determined as accurately as possible. Use of a scale or weight tape is recommended. Underdosing could result in ineffective use and may favour resistance development.
Oral use. A single syringe treats a 700 kg horse. Replace cap after use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 32 days.
Not authorized for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), 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}
Once opened, use within 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
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

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/5002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Container for 20 or 48 syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substance:
Moxidectin 18.92 mg

Excipients qsp:
Benzyl Alcohol (E1519) 37.84 mg
Butylhydroxytoluene 0.114 mg

3. PHARMACEUTICAL FORM

Oral gel.
Pale yellow to yellow, clear gel.

4. PACKAGE SIZE

20 x 14.8g.
48 x 14.8g.

5. TARGET SPECIES

Horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use. A single dose of 400µg moxidectin/kg bodyweight should be administered orally using the calibrated syringe. Before the first dose, hold the syringe with the capped end pointing to the left so that the weight measurements and tick marks (small black lines) can be seen. Set the syringe to zero by moving the dial ring so that 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 veterinary medicinal product, hold the syringe as previously described. 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. The accuracy of the dosing device should be thoroughly checked.

To ensure a correct dosage, the body weight should be determined as accurately as possible.
Use of a scale or weight tape is recommended. The accuracy of the dosing device should be thoroughly checked.
To ensure a correct dosage, the body weight should be determined as accurately as possible. Use of a scale or weight tape is recommended. Underdosing could result in ineffective use and may favour resistance development.

Oral use. A single syringe treats a 700 kg horse. Replace cap after use. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 32 days.
Not authorized for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), 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}
Once opened, use within 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.
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

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/5002

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

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substance mg/g
Moxidectin 18.92

Excipients qsp:
Benzyl alcohol (E1519) 37.84 mg
Butylhydroxytoluene 0.114 mg

3. PHARMACEUTICAL FORM

Oral gel.
Pale yellow to yellow, clear gel.

4. PACKAGE SIZE

1 x 14.8g.

5. TARGET SPECIES

Horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use. A single dose of 400µg moxidectin/kg bodyweight should be administered orally using the calibrated syringe. Before the first dose, hold the syringe with the capped end pointing to the left so that the weight measurements and tick marks (small black lines) can be seen. Set the syringe to zero by moving the dial ring so that 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 veterinary medicinal product, hold the syringe as previously described. 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. The accuracy of the dosing device should be thoroughly checked.

To ensure a correct dosage, the body weight should be determined as accurately as possible.
Use of a scale or weight tape is recommended. Underdosing could result in ineffective use and may favour resistance development.
Oral use. A single syringe treats a 700 kg horse. Replace cap after use. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 32 days.
Not authorized for use in animals producing milk for human consumption.

9. SPECIAL WARNING(S), 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}
Once opened, use within 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
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

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/5002

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

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Moxidectin 18.92 mg/g

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

14.8g syringe

4. ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 32 days.
Not authorized for use in animals producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use within 6 months.
Use by:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
MoxiSolv 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 and manufacturer responsible for batch release:

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MoxiSolv 18.92 mg/g Oral Gel for Horses.
Moxidectin

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

Each g contains:

Active substance:
Moxidectin 18.92 mg

Excipients:
Benzyl alcohol (E1519) 37.84 mg

Oral gel.
Pale yellow to yellow, clear gel.

4. INDICATION(S)

In horses (including 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) L3 stages of small strongyles are eliminated.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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. In case of very high worm burdens, destruction of the parasites may cause a mild transient colic and loose faeces in the treated horse.

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. Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use. A single dose of 400 micrograms (µg) of moxidectin per kilogram (400µg/kg) bodyweight should be administered orally using the calibrated syringe.
Before the first dose, hold the syringe with the capped end pointing to the left so that the weight measurements and tick marks (small black lines) can be seen. 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 10 micrograms moxidectin. Turn the dial ring until the left side of the ring lines up with the weight of the animal. The accuracy of the dosing device should be thoroughly checked.
To ensure a correct dosage, the body weight should be determined as accurately as possible.
Use of a scale or weight tape is recommended. Underdosing could result in ineffective use and may favour resistance development.
A single syringe treats a 700 kg horse.
Replace cap after use.

9. ADVICE ON CORRECT ADMINISTRATION

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 veterinary medicinal 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.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 32 days.
Not authorized for use in animals 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 stated on the carton after "EXP".
The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 6 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Horses;
Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.
Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.
Partial cross-resistance between ivermectin and moxidectin has been reported. Cases of resistance to moxidectin have been reported in equine cyathostomins, *Parascaris equorum, Oxyuris equ*i in the EU and elsewhere. The use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. the Faecal Egg Count Reduction Test (FECRT)). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.
A shorter egg re-appearance periods after treatment with moxidectin is an early indicator of the development of resistance in equine nematodes.

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 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 clinical signs (such as ataxia, muscle tremor and convulsions) and digestive clinical signs (such as hypersalivation) were recorded on very rare occasions. These adverse effects are usually transient and disappear spontaneously in most cases.

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

Moxidectin and the excipients benzyl alcohol, polysorbate 80 and propylene glycol can cause allergic reactions. People with known hypersensitivity to moxidectin or any of the excipients should avoid all contact with the veterinary medicinal product.

This product can cause skin and eye irritation. Avoid direct contact with skin and eyes. Wear protective gloves when handling the veterinary medicinal product. Wash hands after use. In case of skin or eye contact, rinse immediately with a large amount of water. If symptoms persist, seek medical advice and show the package leaflet or the label to the physician.
Do not smoke, drink or eat while handling the product.

Pregnancy and lactation:
The veterinary medicinal product has been shown to be safe for use in pregnant and lactating mares.
Mares may be treated at any stage of pregnancy and lactation.

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

Overdose (symptoms, emergency procedures, 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.

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.

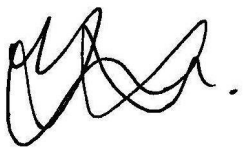
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes:
Box containing 1 syringe.
Container with 10 individually boxed syringes.
Container with 20 individually boxed syringes.
Container with 20 syringes (loose).
Container with 48 syringes (loose).

Not all pack sizes may be marketed.



Approved: 24 January 2023