# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Horse Oral Paste 18.7 mg/g

## 2. STATEMENT OF ACTIVE SUBSTANCES

Contains 18.7 mg/g ivermectin with apple flavour.

## 3. PHARMACEUTICAL FORM

Oral paste

## 4. PACKAGE SIZE

Oral syringe, 6.42 g of product.
Oral syringe, 8,56 g of product.

## 5. TARGET SPECIES

Horses

## 6. INDICATION(S)

For broad spectrum use in parasite control for horses, ponies, mares and foals.
The product kills the adult and 4$^{th}$ larval stages of most of the important internal parasites including small redworms, the arterial stages of the large redworms, lungworms and bots with a single dose.
The product kills adults and immatures (4$^{th}$ larval) small strongyles or cyathostomes unless otherwise stated.
Read the package leaflet before use.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

Meat and offal: 34 days.
Do not use in mares producing milk for human consumption.

## 9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

## 10. EXPIRY DATE

EXP {month/year}
To be used immediately after first opening the oral syringe.

## 11. SPECIAL STORAGE CONDITIONS

None.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used containers.
Any unused product or waste material should be disposed of in accordance with national requirements.

## 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 50146/4036

## 17. MANUFACTURER'S BATCH NUMBER

Batch No.:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Horse Oral Paste 18.7 mg/g

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 18.7 mg/g ivermectin, with apple flavour.

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

6.42g
8.56g

## 4. ROUTE(S) OF ADMINISTRATION

Oral

## 5. WITHDRAWAL PERIOD(S)

Meat and offal 34 days.
Do not use in mares producing milk for human consumption.

## 6. BATCH NUMBER

Batch no.:

## 7. EXPIRY DATE

EXP {month/year}

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:
# Bimectin Horse Oral Paste 18.7 mg/g

## 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, Unit 2/3/4 Airton Close, Tallaght, Dublin 24

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimectin Horse Oral Paste 18.7 mg/g

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

The product is a ready-to-administer, 18.7 mg/g oral paste formulation of ivermectin with apple flavour**.**

## 4. INDICATION(S)

The product is indicated for the treatment of nematode or arthropod infestations in horses due to:

**Large strongyles**
Strongylus vulgaris (adults and 4 $^{th}$ larval [arterial] stages)
S. edentatus (adults and 4$^{th}$ larval [tissue] stages)
S. equinus (adults)
Triodontophorus spp. (adults)
Triodontophorus brevicauda
Triodontophorus serratus

**Small Strongyles**
Adults and immatures (fourth stage larvae) small strongyles or cyathostomes unless otherwise stated. Ivermectin is not effective against the encysted larval stages of the small strongyles.
Coronocyclus spp.
Coronocyclus coronatus
Coronocyclus labiatus
Coronocyclus labratus
Cyathostomum spp.
Cyathostomum catinatum
Cyathostomum pateratum
Cylicocyclus spp.
Cylicocyclus ashworthi
Cylicocyclus elongatus
Cylicocyclus insigne
Cylicocyclus leptostomum
Cylicocyclus nassatus
Cylicostephanus spp.

Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus
Cylicodontophorus spp.
Cylicodontophorus bicornatus
Parapoteriostomum spp.
Parapoteriostomum mettami
Petrovinema spp.
Petrovinema poculatum
Poteriostomum spp.

**Lungworms** (adult and inhibited fourth stage larvae)
Dictyocaulus arnfieldi
**Pinworms** (adult and inhibited fourth stage larvae)
Oxyuris equi
**Ascarids** (adults and third & fourth stage larvae)
Parascaris equorum
**Hairworms** (adults)
Trichostrongylus axei
**Large-mouth stomach worms** (adults)
Habronema muscae
**Neck threadworms** (microfilariae)
Onchocerca spp.
**Intestinal threadworms** (adults)
Strongyloides westeri
**Stomach bots (oral and gastric stages)**
Gasterophilus spp.

## 5. CONTRAINDICATIONS

None.

## 6. ADVERSE REACTIONS

Some horses carrying heavy infection of Onchocerca microfilariae have experienced oedema and pruritus following dosing, assumed to be the result of death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.

## 7. TARGET SPECIES

Horses

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

**Bodyweight and dosage should be accurately determined prior to treatment.**
The smaller syringe contains sufficient paste to treat one 600kg horse, the bigger syringe contains sufficient paste to treat one 800kg horse at the recommended dose rate (200 mcgs of ivermectin per kg of bodyweight).

Each weight marking on the syringe plunger delivers sufficient paste to treat 100kg of bodyweight. Release the knurled ring by making a ¼ turn and slide the ring up the plunger shaft so that the side of the ring nearest the barrel is at the desired weight marking. Turn the knurled ring ¼ turn to lock in place. Make sure the horse's mouth contains no feed. Remove the plastic cap from the tip of the syringe barrel and insert the syringe at the interdental space (the gap between the front and back teeth). Depress the plunger and deposit the paste over the back of the tongue. Immediately raise the horse's head for a few seconds after dosing.
This is a single dose product. Discard after use.
**For Best Results:** The treatment schedule should be based on the local epidemiological situation. For further advice please consult the veterinary surgeon.

## 9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over-dosing.

## 10. WITHDRAWAL PERIOD(S)

Meat and offal 34 days. Do not use in mares producing milk for human consumption.

## 11. SPECIAL STORAGE PRECAUTIONS

For animal treatment only.
Keep out of the reach and sight of children.
To be used immediately after first opening the oral syringe.
Do not use after the expiry date stated on the label and carton after EXP.

## 12. SPECIAL WARNING(S)

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.
- Underdosing, which may be due to underestimation of body weight, or misadministration of the product.

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 tests(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.

Resistance to ivermectin has been reported in Parascaris equorum in horses. Therefore, the use of this product should be based on local farm epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.
The effects of GABA agonists are increased by ivermectin

**User precautions:** Do not smoke, drink or eat while handling the product. Avoid contact with skin and eyes. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and if necessary get medical attention. Wash hands after use.

**Special warnings for non-target species:** The product has been formulated for use in horses only. Cats, Dogs, especially Collies, Old English Sheepdogs and related breed or crosses, and also turtles and tortoises may be adversely affected by the concentration of ivermectin in this product if they are allowed to ingest spilled paste or have access to used syringes.

**Use during pregnancy/ lactation**: Studies performed in laboratory animals showed no teratogenic or embryonic effect of ivermectin at the recommended doses during therapy. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to risk/benefit analysis by the responsible veterinary surgeon.

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

**Environmental Safety:** EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used containers. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2021

## 15. OTHER INFORMATION

Marketing Authorisation number:
Vm 50146/4036

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Legal Category:POM-VPS To be supplied only on veterinary prescription.
Distributor:
Bimeda®, Cross Vetpharm Group UK Ltd.,
Unit 2, Bryn Cefni, Llangefni, Anglesey LL77 7XA, UK

Approved 22 November 2021