

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Molemec Paste for Horses

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Molemec Paste for Horses is a ready-to-use paste formulation containing 18.7 mg/g ivermectin.

### **3. PHARMACEUTICAL FORM**

18.7 mg/g oral paste.

Molemec Paste for Horses is a white ready-to-use paste formulation for oral administration containing ivermectin 18.7 mg/g in disposable polypropylene syringes. Each syringe contains 6.42 g paste.

### **4. PACKAGE SIZE**

6.42 grams  
8.03 grams  
11.77 grams

### **5. TARGET SPECIES**

Horses

### **6. INDICATION(S)**

Parasite control for horses, donkeys, ponies, mares and foals.

Molemec Paste for Horses kills the adult and larval stages of the important internal parasites of horses and donkeys. These include small redworms that are resistant to benzimidazole-based wormers, the arterial stages of the large redworm, lungworms, bots and many others.

Molemec Paste for Horses kills the adult and larval stages of the important internal parasites, including small redworms that are resistant to benzimidazole-based wormers, the arterial stages of large redworms, lungworms and bots, with a single dose.

**BROAD SPECTRUM** - Molemec Paste for Horses kills the adult and larval stages of the important internal parasites including small redworms, the arterial stages of the large redworm, lungworms and bots with a single dose.

CONTROLS RESISTANT SMALL REDWORMS - Molemec Paste for Horses kills the small redworms that are resistant to benzimidazole-based wormers.

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

### **ADMINISTRATION**

Bodyweight and dosage should be accurately determined prior to treatment. For syringes intended to treat horses up to 600 kg and 1100 kg, the contents of one syringe will treat horses up to 600 kg. Calibrated markings are provided at 100 kg bodyweight intervals. For the syringe intended to treat horses up to 750 kg, calibrated markings are provided at 125 kg bodyweight intervals. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger. Release the knurled ring by making a 1/4 turn and sliding the ring up the plunger shaft so that the side nearest the barrel is at the required weight marking. Firmly relock the ring (the arrow heads will now be facing each other). 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.

### **FOR BEST RESULTS**

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations. Foals may be treated initially at 6-8 weeks of age if indicated. Collect droppings from pasture regularly.

### **SAFE**

Molemec Paste for Horses has a wide safety margin. At the recommended rate Molemec Paste for Horses can be used with complete confidence in foals, mares, ponies, donkeys and horses. Mares may be treated at any stage of pregnancy and the fertility of stallions that have been dosed has not been affected.

## **8. WITHDRAWAL PERIOD WITHDRAWAL PERIOD**

Donkeys - meat and offal: 21 days Horses - meat and offal: 21 days

Do not use in mares producing milk for human consumption.

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

See package leaflet for accompanying directions and user warnings. SEALED FOR SECURITY. IF BROKEN DO NOT ACCEPT.

## 10. EXPIRY DATE

Expiry date:

## 11. SPECIAL STORAGE

### CONDITIONS STORAGE

### CONDITIONS

Do not store above 25°C. Protect from light.

Do not use after the expiry date.

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

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

*[Distribution category]*

For Animal Treatment Only.

POM-VPS

## 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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

### **Distributed by:**

Mole Valley Farmers Ltd.  
Station Road  
South Molton  
North Devon  
EX36 3BH

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4250

## 17. MANUFACTURER’S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {SYRINGE LABEL}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Molemec Paste for Horses

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

18.7 mg/g oral paste (ivermectin)

**3. PHARMACEUTICAL FORM**

Oral paste

**4. PACKAGE SIZE**

6.42 grams  
8.03 grams  
11.77 grams

**5. TARGET SPECIES**

Horses

**6. INDICATION(S)**

Parasite control for horses, donkeys, ponies, mares and foals.

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

Read package leaflet before use.

**8. WITHDRAWAL PERIOD**

**Withdrawal Period:** Meat and offal: 21 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**

Expiry Date:

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Protect from light.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

*[Distribution category]*

For animal treatment only.

To be supplied only on veterinary prescription.

POM-VPS

**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**

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

**Distributed by:**

Mole Valley Farmers Ltd.  
Station Road  
South Molton  
North Devon  
EX36 3BH

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 08327/4250

**17. MANUFACTURER’S BATCH NUMBER**

Batch No.:

**PACKAGE LEAFLET FOR:**

Molemec Paste for Horses

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

Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS, 4 Chemin du Calquet  
31000 Toulouse, France

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Molemec Paste for Horses

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

18.7 mg/g oral paste (ivermectin)

**4. INDICATION(S)**

Molemec Paste for Horses kills the adult and arterial larval stages of the important internal parasites of horses and donkeys. These include small redworms that are resistant to benzimidazole-based wormers, the arterial stages of the large redworm, lungworms, bots and many others. The product controls the following horse parasites with one treatment:

**Large strongyles:**

*Strongylus vulgaris* (adults and arterial larval stages)

*Strongylus edentatus* (adults and tissue larval stages) *Strongylus equinus* (adults)

*Triodontophorus* spp. (adults): *Triodontophorus brevicauda*,

*Triodontophorus serratus* *Craterostomum acuticaudatum*

(adults) **Small strongyles. Adult and immature (fourth-stage larvae) small strongyles (cyathostomes), including benzimidazole-resistant strains:**

*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*, *Cylicocyclus radiatus*

*Cylicodontophorus* spp.: *Cylicodontophorus bicornatus*

*Cylicostephanus* spp.: *Cylicostephanus asymmetricus*,

*Cylicostephanus*

*bidentatus*, *Cylicostephanus calicatus*, *Cylicostephanus goldi*,  
*Cylicostephanus longibursatus*, *Cylicostephanus minutus*  
*Gyalocephalus capitatus*

*Parapoteriostomum* spp.: *Parapoteriostomum*  
*euproctus*, *Parapoteriostomum mettami*

*Petrovinema* spp.: *Petrovinema poculatum*

*Poteriostomum* spp.: *Poteriostomum*  
*imparidentatum* **Lungworms** (adult and  
immatures):

*Dictyocaulus arnfieldi*

**Pinworms** (adult and immatures):

*Oxyuris equi*

**Ascarids** (adult and third and 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 of *Gasterophilus* spp.

## 5. CONTRAINDICATIONS

### SPECIAL WARNINGS FOR NON-TARGET SPECIES

The product has been formulated specifically for use in horses and donkeys only. Dogs or cats 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.

## 6. ADVERSE REACTIONS OVERDOSE AND SAFETY MARGIN

Molemec Paste for Horses has a wide safety margin and can be used at the recommended dose with complete confidence in foals, mares, ponies, donkeys and horses. Mild transitory signs (slowed pupillary light response and depression) have been seen at nine times the recommended dose level (i.e. 1.8 mg/kg). Other signs seen at even higher doses include mydriasis (dilated pupils), ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. No antidote has been identified; however, symptomatic therapy may be beneficial.

### NOTE TO USERS

Some horses have experienced reactions involving skin swellings and itching shortly after treatment. In most of these cases the horses have been diagnosed as

carrying heavy infections of *Onchocerca microfilariae* and it is assumed that the reactions were the result of the death of large numbers of microfilariae. Although the signs have resolved within a few days treatment for these symptoms may be advisable.

Consult your veterinary surgeon should these signs persist.

## **7. TARGET SPECIES**

Horses

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

### **DOSAGE AND ADVICE ON CORRECT ADMINISTRATION**

Administer orally to horses and donkeys at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Bodyweight and dosage should be accurately determined prior to treatment. For syringes intended to treat horses up to 600 kg and 1100 kg, the contents of one syringe will treat horses up to 600 kg. Calibrated markings are provided at 100 kg bodyweight intervals. For the syringe intended to treat horses up to 750 kg, calibrated markings are provided at 125 kg bodyweight intervals. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger. Unlock the knurled ring by making a 1/4 turn and slide the ring up the plunger shaft so that the side nearest the barrel is at the required weight marking. Firmly re-lock the ring, (the arrow-heads will now be facing each other). Make sure the horse's mouth contains no feed. Remove the plastic cap from the tip of the nozzle and insert the syringe into the horse's mouth at the interdental space, (the gap between the front and back teeth). Depress the plunger as far as it will go to deposit the paste at the base of the tongue. Immediately raise the horse's head for a few seconds after dosing. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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, misadministration of the product, or lack of calibration of the dosing device.

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. Resistance to macrocyclic lactones (which includes ivermectin) has been reported in *Parascaris equorum* in horses in a number of countries within the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of gastro-intestinal nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

## **USE DURING PREGNANCY AND LACTATION**

Mares may be treated at any stage of pregnancy and the fertility of stallions that have been dosed has not been affected.

## **INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION**

The product has been used in conjunction with other equine health care products and no interactions have been identified.

### **10. WITHDRAWAL PERIOD(S)**

Donkeys - meat and offal: 21 days. Horses - meat and offal: 21 days.  
Do not use in mares producing milk for human consumption.

### **11. SPECIAL STORAGE PRECAUTIONS SPECIAL PRECAUTIONS FOR STORAGE**

Do not store above 25°C. Protect from light. Keep out of the sight and reach of children. Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

### **12. SPECIAL WARNING(S)**

#### **SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE PRODUCT TO ANIMALS**

Do not smoke, eat or drink while handling the product. Wash hands after use. This product may cause skin and eye irritation. Therefore, the user should avoid contact of the product with the skin and the eyes. In the case of contact, rinse immediately with plenty of water. In the case of accidental ingestion or eye irritation after contact seek medical advice immediately and show the package insert or label to the physician. For animal treatment only.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

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

March 2021

**15. OTHER INFORMATION OTHER INFORMATION**

Box of 1 syringe for oral administration of 6.42g  
Box of 1 syringe for oral administration of 8.03g  
Box of 1 syringe for oral administration of 11.77g  
Box of 50 syringes for oral administration of 6.42g  
Box of 50 syringes for oral administration of 8.03g  
Box of 50 syringes for oral administration of 11.77g Not all pack sizes may be marketed

POM-VPS

To be supplied only on veterinary prescription.

Vm 08327/4250

Approved 14 April 2022

