

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box (of 1 or 50 Syringes)

CASE N°1: *The text below corresponds to the cases where all the information of the package leaflet can not be conveyed on the outer packaging and the container (for example for multilingual packaging). Consequently a package leaflet is added (see the corresponding template).*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOLEMEC PLUS Paste for Horses 15.5 mg/g / 77.5 mg/g Oral Paste
EQVALAN DUO EQUIPACK (France)

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Ivermectin: 15.5 mg

Praziquantel: 77.5 mg

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

1 syringe of 7.74 g

1 syringe of 9.68 g

1 syringe of 14.19 g

50 syringes of 7.74 g

50 syringes of 9.68 g

50 syringes of 14.19 g

5. TARGET SPECIES

Horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Meat and offal: 30 days

Do not use in mares producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 2 years

11. SPECIAL STORAGE CONDITIONS

Store in the original container. Replace the cap after use.

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

Disposal: read package leaflet.

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

For animal treatment only.

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4252

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box (of 1 or 50 syringes)

CASE N°2: The text below corresponds to the cases where all the information of the package leaflet CAN be conveyed on the outer packaging and container.
Consequently, in that case, no separate leaflet is provided in compliance with the current QRD Template

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Molemec Plus Paste for Horses 15.5 mg/g / 77.5 mg/g Oral Paste
Eqvalan Duo Equipack (France)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each g contains:

Ivermectin: 15.5 mg

Praziquantel: 77.5 mg

Excipients: Sunset yellow FCF (E110), Titanium oxide (E171), Butylhydroxyanisole (E320)

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

1 syringe of 7.74 g

1 syringe of 9.68 g

1 syringe of 14.19 g

50 syringes of 7.74 g

50 syringes of 9.68 g

50 syringes of 14.19 g

5. TARGET SPECIES

Horses

6. INDICATION(S)

For the treatment of mixed cestode and nematode or arthropod infestations in horses.
The following parasites of horses are sensitive to the antiparasitic effects of the product:

Adult Tapeworms: *Anoplocephala perfoliata*, *Anoplocephala magna*.

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).

Adult and immature (intraluminal fourth-stage larvae) of small strongyles or cyathostomes, including benzimidazole-resistant strains: *Coronocyclus* spp., *Coronocyclus coronatus*, *Coronocyclus labiatus*, *Coronocyclus labratus*, *Cyathostomum* spp., *Cyathostomum catinatum*, *Cyathostomum pateratum*, *Cylicocyclus* spp., *Cylicocyclus ashworthi*, *Cylicocyclus elongates*, *Cylicocyclus insigne*, *Cylicocyclus leptostomum*, *Cylicocyclus nassatus*, *Cylicodontophorus* spp., *Cylicodontophorus bicornatus*, *Cylicostephanus* spp., *Cylicostephanus calicatus*, *Cylicostephanus goldi*, *Cylicostephanus longibursatus*, *Cylicostephanus minutus*, *Parapoteriostomum* spp., *Parapoteriostomum mettami*, *Petrovinema* spp., *Petrovinema poculatum*, *Poteriostomum* spp., **Adult hairworms:** *Trichostrongylus axei*. **Adult and immature (fourth stage Larvae) pinworms:** *Oxyuris equi*. **Adult, third- and fourth-stage larvae of roundworms (ascarids):** *Parascaris equorum*. **Microfilariae of neck threadworms:** *Onchocerca* spp. **Adult intestinal threadworms:** *Strongyloides westeri*. **Adult large-mouth stomach worms:** *Habronema muscae*. **Oral and, gastric stages of bots:** *Gasterophilus* spp. **Adult and immature (inhibited fourth stage larvae) lungworms:** *Dictyocaulus arnfieldi*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use

The recommended dosage is 200 mcg ivermectin per kilogram of bodyweight and 1mg praziquantel per kilogram of bodyweight corresponding to 1.29 g of paste per 100 kg bodyweight in a single administration.

Bodyweight and dosage should be accurately determined prior to treatment. For syringes intended to treat horses up to 600 kg and 1100 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.

Parasite control Program

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations.

Advice on correct administration

The product is for oral administration only. While holding the plunger, turn the knurled ring on the plunger $\frac{1}{4}$ turn to the left and slide it so the stop ring is at the prescribed weight marking. Lock the ring in place by turning it $\frac{1}{4}$ turn to the right in order to bring the two arrows, the one visible on the ring and the one on the plunger rod, into alignment. Make sure the horse's mouth contains no feed. Remove the cover from the tip of the syringe. Insert the syringe tip into the horse's mouth at the interdental space and deposit the paste on the base of the tongue. Immediately raise the horse's head for a few seconds after dosing and ensure that the paste is consumed

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 30 days.

Do not use in mares producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications

Do not use in cases of hypersensitivity to active ingredients or to any of the excipients

Adverse reactions

Some horses with heavy infections of *Onchocerca* spp. microfilariae have experienced oedema and pruritis following treatment; such reactions were assumed to be the result of the death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.

Following administration of the product, there have been rare reports of inflammation of the mouth, lip and tongue which results in various clinical signs such as oedema, hypersalivation, erythema, tongue disorder and stomatitis. These reactions have been transitory in nature, appearing within 1 hour and abating within 24 to 48 hours following administration. In case of severe oral reactions symptomatic treatment is recommended.

Digestive discomfort (colic, loose stool) has been observed in very rare cases based on post-marketing surveillance data.

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.

Special warnings

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 bodyweight, 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

Resistance to macrocyclic lactones (which includes ivermectin) has been reported in *Parascaris equorum* in horses in 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.

Special precautions for use in animals

Safety studies were not conducted in foals younger than 2 months of age, or in stallions, the use of the product is not recommended in these categories of animals.

Avermectins may not be well tolerated in all non target animals. Cases of intolerance are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtle and tortoises.

Dogs and cats should not be allowed to ingest spilled paste or access to used syringes due to the potential for adverse effects related to ivermectin toxicity.

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

Wash hands after use.

Do not smoke, drink or eat while handling the product.

This product may cause skin and eye irritation. Therefore, the user should avoid contact of the product with the skin and the eyes. In 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 the label to the physician.

Pregnancy and lactation

Studies performed in laboratory animals showed no teratogenic or embryotoxic effect of either ivermectin or praziquantel at the recommended doses during therapy.

Ivermectin-Praziquantel combination can be used after the first three months of gestation and during lactation. In the absence of clinical data in early pregnancy the product can only be used in the first three months of gestation according to a risk benefit analysis by the veterinarian.

Overdose (symptoms, emergency procedures, antidotes), if necessary

No undesirable effects related to treatment were observed in 2 months old horses treated with the product at up to three times the recommended dose and in adult horses treated at ten times the recommended dose.

Transient decreased food consumption, increased body temperature, salivation and impairment of vision were noticed in horses treated twice with an ivermectin oral paste or once with the product at ten times the recommended dose (i.e., 2 mg/kg b.w.). All changes disappeared within five days.

No antidote has been identified; however, symptomatic therapy may be beneficial.

Interaction with other medicinal products and other forms of interaction

No data available

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 2 years

11. SPECIAL STORAGE CONDITIONS

Store in the original container. Replace the cap after use. Do not use after the expiry date which is stated on the label after EXP.
Shelf life after first opening the immediate packaging: 2 years

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

EXTREMELY DANGEROUS FOR FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used syringes. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product 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

For animal treatment only

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 AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer responsible for batch release
Boehringer Ingelheim Animal Health France SCS
4 chemin du Calquet
31300 Toulouse, France

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4252

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Syringe label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MOLEMEC PLUS Paste for Horses 15.5 mg/g / 77.5 mg/g Oral Paste
EQVALAN DUO EQUIPACK (France)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin 15.5 mg/g
Praziquantel 77.5 mg/g

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

Syringe of 7.74 g of paste
Syringe of 9.68 g of paste
Syringe of 14.19 g of paste

4. ROUTE(S) OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Meat and offal: 30 days
Do not use in mares producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use within 2 years

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR
Molemec Plus Paste for Horses 15.5 mg/g / 77.5 mg/g Oral Paste

The leaflet described below applies to Case N°1 where a package leaflet is added in the packaging.

In Case N°2 no leaflet is needed.

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, UK

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 Plus Paste for Horses 15.5 mg/g / 77.5 mg/g Oral Paste

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

Each g contains:

Ivermectin 15.5 mg

Praziquantel 77.5 mg

Excipients include colorants (sunset yellow FCF (E110), titanium oxide (E171)) and antioxidant (butylhydroxyanisole (E320)).

4. INDICATION(S)

For the treatment of mixed cestode and nematode or arthropod infestations in horses.

The following parasites of horses are sensitive to the antiparasitic effects of the product:

Adult Tapeworms: *Anoplocephala perfoliata*, *Anoplocephala magna*.

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).

Adult and immature (intraluminal fourth-stage larvae) of small strongyles or cyathostomes, including benzimidazole-resistant strains: *Coronocyclus* spp., *Coronocyclus coronatus*, *Coronocyclus labiatus*, *Coronocyclus labratus*, *Cyathostomum* spp., *Cyathostomum catinatum*, *Cyathostomum pateratum*, *Cylicocyclus* spp., *Cylicocyclus ashworthi*, *Cylicocyclus elongates*, *Cylicocyclus insigne*, *Cylicocyclus leptostomum*, *Cylicocyclus nassatus*, *Cylicodontophorus* spp., *Cylicodontophorus bicornatus*, *Cylicostephanus* spp., *Cylicostephanus calicatus*, *Cylicostephanus goldi*, *Cylicostephanus longibursatus*, *Cylicostephanus minutus*, *Parapoteriostomum* spp., *Parapoteriostomum mettami*, *Petrovinema* spp., *Petrovinema poculatum*, *Poteriostomum* spp.,

Adult hairworms: *Trichostrongylus axei*.

Adult and immature (fourth stage Larvae) pinworms: *Oxyuris equi*.

Adult, third- and fourth-stage larvae of roundworms (ascarids): *Parascaris equorum*.

Microfilariae of neck threadworms: *Onchocerca* spp.

Adult intestinal threadworms: *Strongyloides westeri*.

Adult large-mouth stomach worms: *Habronema muscae*.

Oral and, gastric stages of bots: *Gasterophilus* spp.

Adult and immature (inhibited fourth stage larvae) lungworms: *Dictyocaulus arnfieldi*.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to active ingredients or to any of the excipients

6. ADVERSE REACTIONS

Some horses with heavy infections of *Onchocerca* spp. microfilariae have experienced oedema and pruritis following treatment; such reactions were assumed to be the result of the death of large numbers of microfilariae. These signs resolve within a few days but symptomatic treatment may be advisable.

Following administration of the product, there have been rare reports of inflammation of the mouth, lip and tongue which results in various clinical signs such as oedema, hypersalivation, erythema, tongue disorder and stomatitis. These reactions have been transitory in nature, appearing within 1 hour and abating within 24 to 48 hours following administration. In case of severe oral reactions symptomatic treatment is recommended.

Digestive discomfort (colic, loose stool) has been observed in very rare cases based on post-marketing surveillance data.

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

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

Oral use

The recommended dosage is 200 mcg ivermectin per kilogram of bodyweight and 1mg praziquantel per kilogram of bodyweight corresponding to 1.29 g of paste per 100 kg bodyweight in a single administration.

Bodyweight and dosage should be accurately determined prior to treatment. For syringes intended to treat horses up to 600 kg and 1100 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.

Parasite control Program

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control for both tapeworm and roundworm infestations.

9. ADVICE ON CORRECT ADMINISTRATION

The product is for oral administration only. While holding the plunger, turn the knurled ring on the plunger $\frac{1}{4}$ turn to the left and slide it so the stop ring is at the prescribed weight marking. Lock the ring in place by turning it $\frac{1}{4}$ turn to the right in order to bring the two arrows, the one visible on the ring and the one on the plunger rod, into alignment. Make sure the horse's mouth contains no feed. Remove the cover from the tip of the syringe. Insert the syringe tip into the horse's mouth at the interdental space and deposit the paste on the base of the tongue. Immediately raise the horse's head for a few seconds after dosing and ensure that the paste is consumed.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 30 days.

Do not use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original container.

Replace cap after use.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 2 years

12. SPECIAL WARNING(S)

Special warnings

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 (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.

Resistance to macrocyclic lactones (which includes ivermectin) has been reported in *Parascaris equorum* in horses in 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

Special precautions for use in animals

Safety studies were not conducted in foals younger than 2 months of age, or in stallions, the use of the product is not recommended in these categories of animals. Avermectins may not be well tolerated in all non target animals. Cases of intolerance are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtle and tortoises.

Dogs and cats should not be allowed to ingest spilled paste or access to used syringes due to the potential for adverse effects related to ivermectin toxicity.

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

Wash hands after use.

Do not smoke, drink or eat while handling the product.

This product may cause skin and eye irritation. Therefore, the user should avoid contact of the product with the skin and the eyes. In 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 the label to the physician.

Pregnancy and lactation:

Studies performed in laboratory animals showed no teratogenic or embryotoxic effect of either ivermectin or praziquantel at the recommended doses during therapy. Ivermectin-Praziquantel combination can be used after the first three months of gestation and during lactation. In the absence of clinical data in early pregnancy the product can only be used in the first three months of gestation according to a risk benefit analysis by the veterinarian.

Overdose (symptoms, emergency procedures, antidotes)

No undesirable effects related to treatment were observed in 2-month-old horses treated with the product at up to three times the recommended dose and in adult horses treated at ten times the recommended dose.

Transient decreased food consumption, increased body temperature, salivation and impairment of vision were noticed in horses treated twice with an ivermectin oral paste or once with the product at ten times the recommended dose (i.e., 2 mg/kg b.w.). All changes disappeared within five days.

No antidote has been identified; however, symptomatic therapy may be beneficial.

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

EXTREMELY DANGEROUS FOR FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used syringes. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

1 or 50 syringes of 7.74g, 9.68 g or 14.19 g of oral paste.

Not all pack sizes may be marketed.

Approved 10 August 2023

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.