

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strongid-P Paste 43.90% w/w
pyrantel embonate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each oral doser contains 11.41g pyrantel embonate in 26g paste.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

5. TARGET SPECIES

6. INDICATION(S)

Broad-spectrum Horse Wormer for Oral Use

For the control and treatment of adult infections of large and small redworms (strongyles), including benzimidazoleresistant strains, the large roundworm (*Parascaris equorum*) and pinworm or seatworm (*Oxyuris equi*) dose at a rate of 19mg pyrantel embonate per kg bodyweight. For example: Body weight 600kg, dose one full oral doser.

To include the control of tapeworm (*Anoplocephala perfoliata*) the dose should be doubled.

For example: Body weight 600kg, dose 2 full oral dosers.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See carton for dosage table.

See oral doser carton for full directions for use.

8. WITHDRAWAL PERIOD

Withdrawal period: Horse meat - zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid contact with the skin. Wash hands and any other parts of the body which come into contact with the product.

10. EXPIRY DATE

Exp. date

After first opening, use by:

Any product remaining 2 months after first opening should be discarded.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C and protect from direct sunlight. Store in tightly closed original container.

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

Any unused veterinary medicinal products 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

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

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4176

17. MANUFACTURER’S BATCH NUMBER

Lot No.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
DISPLAY CARTON**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strongid-P Paste 43.90% w/w
pyrantel embonate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each oral doser contains 11.41g pyrantel embonate in 26.00g (22ml) paste..

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

Contents: 10 oral dosers

5. TARGET SPECIES

6. INDICATION(S)

An easily administered broad-spectrum equine anthelmintic, presented in a disposable plastic oral doser.

Broad-spectrum Wormer for Oral Use

Dosage: For the control and treatment of adult infections of large and small redworms (strongyles) including benzimidazole-resistant strains, the large roundworm (*Parascaris equorum*) and pinworm or seatworm (*Oxyuris equi*) dose at a rate of 19mg pyrantel embonate per kg body weight. To include control of tapeworm (*Anoplocephala*) the dose should be doubled. For example: Body weight 600kg, dose 2 full oral dosers.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSE TABLE FOR STRONGID-P PASTE FOR CONTROL OF ROUNDWORMS

Class of Horse	Height in Hands	Weight in Kg	Strongid-P Dose In Oral Dosers
Heavy Hunters	16+	600-700	1.25 oral dosers
Thoroughbreds, Hunters Hacks, Arabs	14.2-16.2	450-600	1 oral dose
Ponies	12.2-14.2	300-450	0.75 oral doser
Small Ponies and Donkeys	9.0-12.2	150-300	0.5 oral doser
Miniature Ponies	Less than 9.0	Up to 150 kg	0.25 oral doser

Two treatments per year are recommended; one in July and one in October.

8. WITHDRAWAL PERIOD

Horse meat- zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid contact with skin. Wash hands and any other parts of the body which come into contact with the product. Only for direct oral administration.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from direct sunlight.

12. SPECIAL 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

For animal treatment only.

For Conditions of Sale see Price List. Full directions for use enclosed.

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

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17. MANUFACTURER’S BATCH NUMBER

LOT

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strongid-P Paste 43.90% w/w
pyrantel embonate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Strongid-P a pale yellow to buff paste is presented in an easy to use, disposable, plastic oral doser containing 11.41g pyrantel embonate in 26.00g (22ml) paste.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

5. TARGET SPECIES

6. INDICATION(S)

WHY USE STRONGID-P?

Broad-spectrum activity

Strongid-P is effective against all the important gut-dwelling roundworms found in the horse, and also tapeworms when twice the normal dose level is used.

Effective against benzimidazole-resistant small redworms

Strongid-P is effective against benzimidazole-resistant strains of small redworms.

Safety

Strongid-P is safe to give horses, including young foals of over four weeks of age, pregnant mares, and stallions, providing the recommendations are followed. Strongid-P a pale yellow to buff paste is presented in an easy to use, disposable, plastic oral doser containing 11.41g pyrantel embonate in 26.00g (22ml) paste.

USES

To effectively control all important gut-dwelling roundworms found in horses and equine tapeworms when twice the normal dose level is used. The broad-spectrum activity includes:

Large Roundworms

Parascaris equorum.

Large Redworms

(large strongyles) *Strongylus vulgaris*, *Strongylus edentatus*, *Strongylus equinus* and *Triodontophorus* spp.

Small Redworms

(small strongyles including benzimidazole-resistant strains) *Cyathostomum* spp.

Seatworms/pinworms *Oxyuris equi*.

Tapeworms *Anoplocephala perfoliata*.

Effective against all the important gut-dwelling roundworms.

Effective against tapeworms when used at twice the normal dose.

Broad-spectrum anthelmintic for use in horses, ponies, donkeys and foals over four weeks of age.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION

Administration

Strongid-P is recommended for direct oral administration in horses, ponies, donkeys and foals over four weeks of age. It is not necessary to withhold any feed prior to administration, or change normal exercise routines following dosing. The following method of administration is recommended:

1. Position the locking ring over the appropriate mark on the plunger.
2. Remove the cap from the nozzle.
3. The paste is best deposited on the upper surface of the tongue. Introduce the nozzle end of the oral doser at the corner of the mouth. Direct the oral doser backwards and depress the plunger to deposit the paste onto the tongue. Providing the paste is given in this way it is unlikely that any rejection will occur. Raising of the horse's head by a hand under the chin sometimes helps with swallowing.
4. Store in tightly closed original container. Any product remaining 2 months after opening should be discarded.
5. The same oral doser should only be used to dose two animals if they are both healthy and are either running together, or are in direct contact with each other.

Dosage: For the control and treatment of adult infections of large and small redworm, including benzimidazole-resistant strains, the large roundworm and pinworm or seatworm.

See dosage table on side of box.

Dosage to include the control of tapeworms:

To include the control of tapeworm the dose should be doubled. Two treatments per year are recommended; one in July and one in October.

Dosing programmes:

Foals: One to eight months of age. Dose every four weeks.

Horses or ponies: Over eight months of age. Routinely dose every six to eight weeks, but during the summer when at grass dose every four to six weeks. Always dose before

turning out and when stabling for the winter.

Suckler mares: A reduction of redworm challenge to the suckling foal at pasture can be achieved by using clean pasture (reseeded or not grazed the previous year by horses), dosing the mare three to four weeks before turning out and then at monthly intervals until the end of autumn. Ideally mares with foals should go out to clean pasture or, if this is not possible delay turning out until June.

**DOSE TABLE FOR STRONGID-P PASTE FOR CONTROL OF ROUNDWORMS
N.B. TO INCLUDE CONTROL OF TAPEWORM PLEASE DOUBLE THE USUAL
ROUNDWORM DOSE**

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Class of Horse	Height in Hands	Weight in Kg	Strongid-P Dose In Whole Oral Dosers
Heavy Hunters	16+	600-700	1.25 oral dosers
Thoroughbreds, Hunters Hacks, Arabs	14.2-16.2	450-600	1 oral dose
Ponies	12.2-14.2	300-450	0.75 oral doser
Small Ponies and Donkeys	9.0-12.2	150-300	0.5 oral doser
Miniature Ponies	Less than 9.0	Up to 150 kg	0.25 oral doser

8. WITHDRAWAL PERIOD

Horse meat - zero days.

9. SPECIAL WARNING(S), IF NECESSARY

PRECAUTIONS

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 pyrantel has been reported in cyathostomes in horses in a number of countries, including the EU. Therefore the use of this product should be based on a local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Avoid contact with skin.

Wash hands and any other parts of the body which come into contact with the product.

Only for direct oral administration.

Impaction of the small intestine may occur in foals, infected with high numbers of *Parascaris equorum*. Symptoms (colic) may be seen as soon as 30 minutes after treatment.

Combined administration of pyrantel and levamisole or piperazine is not recommended.

10. EXPIRY DATE

Any product remaining 2 months after opening should be discarded.

Expiry Date.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from direct sunlight.

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

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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

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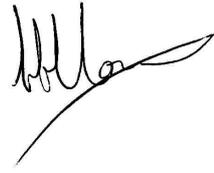
16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4176

17. MANUFACTURER’S BATCH NUMBER

Lot Number.

Revised: November 2022
AN: 01625/2022

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves upwards and to the right.

Approved 11 November 2022