A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON OF 20 SYRINGES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alverin 18.7 mg/g Oral Paste for Horses.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin: 18.7mg/g

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

1 x 6.42 g syringe
20 x 6.42 g syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer orally at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight.

Each syringe delivers 120 mg ivermectin, sufficient to treat 600 kg of bodyweight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 21 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: end MM/YY

This is a single use product. Replace cap and discard contents after use.

11. SPECIAL STORAGE CONDITIONS

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
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

(restrictions or conditions regarding supply and use: dependent on territory)

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

To be completed nationally.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

BN:
With Apple Flavour

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1 syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alverin 18.7 mg/g Oral Paste for Horses.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin: 18.7mg/g

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

6.42g

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer orally at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight.

Each syringe delivers 120 mg ivermectin, sufficient to treat 600 kg of bodyweight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 21 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: end MM/YY

This is a single use product. Replace cap and discard contents after use.

11. SPECIAL STORAGE CONDITIONS

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

ENVIRONMENTAL SAFETY
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
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

(restrictions or conditions regarding supply and use: dependent on territory)

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

BN:
With Apple Flavour

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alverin 18.7 mg/g Oral Paste for Horses, Ivermectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ivermectin 18.7 mg/g

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

6.42g

4. ROUTE(S) OF ADMINISTRATION

Oral Paste.

5. WITHDRAWAL PERIOD

Meat and offal: 21 days

Do not use in mares producing milk for human consumption

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

Expiry: end MM/YY
This is a single use product. Replace cap and discard contents after use.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

(restrictions or conditions regarding supply and use: dependent on territory)

Parasite control for horses.

With Apple Flavour

PACKAGE LEAFLET

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

Manufacturer responsible for batch release:
Cross Vetpharm Group Ltd. Broomhill Road, Tallaght, Dublin 24.

Marketing Authorisation Holder:
(dependent on territory)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alverin 18.7 mg/g Oral Paste for Horses
Ivermectin 18.7 mg/g

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS.

Active substance:
Ivermectin: 18.7 mg/g.

4. INDICATION(S)

The product is indicated for the treatment of parasitic infestations in horses due to:

Large strongyles
Strongylus vulgaris (adults and arterial larval stages)
S. edentatus (adults & tissue larval stages)
S. equinus (adults)
Triodontophorus spp. (adults)
- *Triodontophorus brevicauda*
- *Triodontophorus serratus*

Craterostomum acuticaudatum (adults)

Small Strongyles
Adult and immature (fourth stage larvae) 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 elongatus*
- *Cylicocyclus insigne*
- *Cylicocyclus leptostomum*

Cylicocyclus nassatus
Cylicocyclus radiatus
Cylicostephanus spp.
Cylicostephanus asymetricus
Cylicostephanus bidentatus
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus
Cylicodontophorus spp.
Cylicodontophorus bicornatus
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 (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 of *Gastrophilus* spp.

5. CONTRAINDICATIONS

Not for use in species other than the target species as severe adverse reactions, including fatalities in dogs may occur.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

Administer orally at the recommended dose level of 0.2 mg ivermectin per kilogram of bodyweight. Each syringe delivers 120 mg ivermectin, sufficient to treat 600 kg of bodyweight.

Dosing instructions
Each weight marking on the syringe plunger will deliver sufficient paste to treat 100 kg bodyweight. Unlock the knurled ring by making 1/4 turn and slide the knurled ring up the plunger shaft so that the side nearest the barrel is at the prescribed weight marking. Turn the knurled ring 1/4 turn to lock in place. Remove the plastic cap from the tip of the nozzle. Make sure the horse's mouth contains no feed. Insert the syringe into the horse's mouth at the interdental space. Advance the plunger as far as it will go, depositing the medication on the base of the tongue.

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 overdosing.

10. WITHDRAWAL PERIOD

Meat and offal: 21 days

Do not use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
For animal treatment only.

This is a single use product. The cap should be replaced after use and remaining product should be discarded.
Do not use this veterinary medicinal product after the expiry date which is stated on the label/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, 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.

Veterinary advice should be given on appropriate dosing programs and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. In the event that a product is suspected of being ineffective, the animal owner is advised to seek veterinary advice.

Special Precautions for Use

i. Special precautions for use in animals

Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

The product has been formulated specifically for use in horses only. Dogs and cats (especially Collies, Old English Sheep dogs and related breeds 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.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

ii. User Warnings

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 the label to the physician

iii. Other precautions.

Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

Use during pregnancy and lactation

Can be used in pregnant mares and in breeding stallions.

Interaction with other medicinal products and other forms of interaction

Ivermectin increases the effects of GABA agonists.

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

Mild transitory signs (slowed pupillary light response and depression) have been seen at a dose of 1.8 mg/kg (9 times the recommended dose level). Other signs seen at higher doses include mydriasis, ataxia, tremors, stupor, coma and death. The less severe signs have been transitory. No antidote has been identified; however, symptomatic therapy may be beneficial.

Major Incompatibilities

Not applicable.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
Do not contaminate ponds, waterways or ditches with the product or used container.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Date:

15. OTHER INFORMATION

(restrictions or conditions regarding supply and use: dependent on territory)

Pack size: *Carton containing 1 syringe*
Carton containing 20 syringes
Not all pack sizes may be marketed.