LABEL

NOROMECTIN PREMIX 6 mg/g Premix for Medicated Feeding Stuff for Swine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Premix 6 mg/g Premix for Medicated Feeding Stuff for Swine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin 6 mg/g

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

4. PACKAGE SIZE

1 kg and 5 kg.

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Noromectin Premix for Swine is indicated for the treatment of the following gastrointestinal roundworms, lungworms, lice and mange in adult and growing pigs

Gastrointestinal worms: *Ascaris suum* (adults and fourth-stage larvae), *Hyostrongylus rubidus* (adults and fourth-stage larvae), *Oesophagostomum* spp (adults and fourth-stage larvae), *Strongyloides ransomi* (adults)
Lungworms: *Metastrongylus* spp
Lice: *Haematopinus suis*
Mange mites: *Sarcoptes scabiei* var *suis*
Noromectin Premix for Swine given to pregnant sows before farrowing effectively controls transmission via the milk of *S. ransomi* to piglets.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Noromectin Premix for Swine must be incorporated in feed and fed to animals for seven consecutive days at the recommended dose rate of 100 μg of ivermectin per kg of bodyweight per day.

Read package leaflet before use

8. WITHDRAWAL PERIOD

Foodstuffs must not be taken for human consumption during the treatment period.

Meat and Offal: 12 days.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

Do not use in animals known to be sensitive to the active substance.

IMPORTANT: Read package leaflet before use.

10. EXPIRY DATE

EXP:

Shelf-life after incorporation into meal or pelleted feed: 3 months

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

To ensure thorough dispersion of the product, it should first be mixed with a suitable quantity of feed ingredients before incorporation in the final mix.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, if applicable

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container. Treated animals should not have direct access to surface water and ditches during treatment. Manure of treated animals should not be spread onto land where surface run-off may occur. Any unused veterinary medicinal product or

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

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

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

For animal treatment only.

POM-VPS

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Republic of Ireland

(UK) Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4272

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PACKAGE LEAFLET

NOROMECTIN PREMIX 6 mg/g Premix for Medicated Feeding Stuff for Swine

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

Marketing Authorisation Holder:
(UK) Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Republic of Ireland

Batch Release:
Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noromectin Premix 6 mg/g Premix for Medicated Feeding Stuff for Swine

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

Active substance
Ivermectin 6 mg/g

4. INDICATION(S)

Noromectin Premix for Swine is indicated for the treatment of the following gastrointestinal roundworms, lungworms, lice and mange in adult and growing pigs:

Gastrointestinal worms:
Ascaris suum (adults and fourth-stage larvae)
Hyostrongylus rubidus (adults and fourth-stage larvae)
Oesophagostomum spp (adults and fourth-stage larvae)
Strongyloides ransomi (adults)

Lungworms
Metastrongylus spp (adults)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var *suis*

Noromectin Premix for Swine given to pregnant sows before farrowing effectively controls transmission via the milk of *S. ransomi* to piglets.

5. CONTRAINDICATIONS

Avermectins may not be well tolerated in all non-target species (cases of intolerance with fatal outcome are reported in dogs – especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtle / tortoises).

Do not use in animals known to be hypersensitive to the active substance, or to any of the excipients.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Pigs

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

In-feed use. For the production of medicated feedingstuff.

The product can be incorporated into meal feed or pelleted feed.

0.1mg ivermectin per kg bodyweight per day (equivalent to 16.7mg Noromectin Premix for Swine per kg bodyweight per day) administered for 7 consecutive days.

The dosage per tonne of feedingstuff (inclusion rate) should be adjusted to the current actual daily feed intake of the animals since this varies depending on age, general health, category of animals and animal husbandry (e.g. different environmental temperature, different feeding regime).

To ensure thorough dispersion, 0.333kg or 1.67 kg of the product (depending on weight of pigs) should be first mixed with 5kg feed ingredients before incorporation into the final mix.

This product should be incorporated by licensed feed manufacturers only. The product can be incorporated in pelleted feed preconditioned with steam for up to 10 seconds at a temperature not exceeding 85ºC.

The appropriate inclusion rate per kilogramme or tonne of feed can be calculated as follows:

$$\frac{\text{16.7mg Noromectin Premix for Swine per kg bodyweight per day} \times \text{Heaviest pig bodyweight (kg)}}{\text{Average daily feed intake (kg per animal)}} = \text{mg Noromectin Premix for Swine per kg of feed} = \text{g Noromectin Premix for Swine per t of feed}$$

Growing Pigs: The recommended dose level of 100 μg/kg is obtained under most circumstances for pigs up to 40 kg bodyweight by including 333 g of the product in each tonne of final feed. The ivermectin should be thoroughly mixed in the finished feed and fed continuously as the only ration for seven consecutive days. In pigs weighing more than 40 kg, average daily feed consumption may fall below 5% of bodyweight, particularly if they are on a restricted feeding programme or where pigs are fed a high protein ration. Therefore for pigs weighing 40 kg to 100 kg, include 400 g of the product per tonne of feed.

Adult Pigs: The recommended dose level for adult pigs weighing over 100kg liveweight is achieved in most circumstances by thoroughly mixing 1.67 kg the product in each tonne of finished feed. The resulting medicated feed should be fed at a rate of 1 kg per 100 kg bodyweight for seven days as part of the

individual ration. Where medicated feed is fed as part of the ration, it is recommended that the ivermectin medicated feed is fed first. After this is consumed, any remaining daily feed allocation should be given. This should be repeated for seven consecutive days. Alternatively where dry feed intake can be accurately measured and all the animals to be treated have a similar bodyweight, the inclusion rate can be calculated using the previous formula. This assumes the total ration is to be medicated.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. When treating groups of pigs, ensure they are grouped by weight and dose to the heaviest pig in the group.

The treatment schedule should be based on the local epidemiological situation.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure thorough dispersion, 0.333kg or 1.67kg of the product (depending on weight of pigs) should first be mixed with 5kg of feed ingredients before incorporation into the final mix. The product will remain stable in the finished feed for three months and when stored below 25^{o}C. The product can be incorporated in pelleted feed preconditioned with steam for up to 10 seconds at a temperature not exceeding 85^{o}C.

This product should be incorporated by licensed feed manufacturers only.

Note 1
Exposure of treated pigs to infected animals, contaminated premises, soil or pasture may result in reinfestation and retreatment may be necessary.

Note 2
Since the effect of ivermectin on mange mites is not immediate, avoid direct contact between treated and untreated pigs for at least one week after completion of treatment. Treated pigs can be transferred to clean pens or grouped with uninfected pigs only one week after completion of treatment.

Note 3
Louse eggs are unaffected by treatment.

10. WITHDRAWAL PERIOD

Meat and Offal: 12 days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Keep out of reach and sight of children.
Do not use after the expiry date which is stated on the label.
Shelf-life after incorporation into meal or pelleted feed: 3 months

12. OPERATOR WARNINGS

Do not smoke, drink or eat while handling the product. Wash hands after use. Mixing of the product with feed must take place in a well ventilated area. Avoid contact with skin and eyes. In case of accidental contact, wash the affected area thoroughly with clean running water. If eye irritation persists, seek medical advice.

13. SPECIAL WARNINGS

Severely diseased animals with reduced appetite/anorexia should be treated parenterally.

Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

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.

At the recommended dose rate, no adverse effects on fertility or gestation in breeding animals were observed. The product can be administered during lactation.

No clinically significant signs of intolerance were observed when the product was administered orally to swine at up to 3 times the normal therapeutic dose.

As ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface waters and ditches.

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 effects of GABA agonists are increased by ivermectin.

No antidote has been identified. If suspected toxic reactions occur, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

For animal treatment only.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container. Treated animals should not have direct access to surface water and ditches during treatment. Manure of treated animals should not be spread onto land where surface run-off may occur. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

16. OTHER INFORMATION

Packaging quantities:
1 kg 4-ply kraft paper bags
5 kg 4-ply kraft paper bags

Not all pack sizes may be marketed.

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Approved: 30 July 2019