IMMEDIATE PACKAGE

5 kg foil bag – heat sealed

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

5 kg foil bag – heat sealed

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 6 mg/g Premix for medicated feeding stuff for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Ivermectin 6 mg/g

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

5 kg

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Antiparasitic treatment for Pigs. Read the outer package before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration to pigs mixed in feed

8. WITHDRAWAL PERIOD

Meat and offal: 12 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

MM/YYYY

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place Store in the original outer bag After incorporation into feed, use medicated feed within 8 weeks if meal and 4 weeks if pelleted.

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

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

ECO Animal Health Ltd. The Grange 100 High Street London N14 6BN United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13277/4020

17. MANUFACTURER'S BATCH NUMBER

IMMEDIATE PACKAGE

333 g foil sachet – heat sealed

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

333 g foil sachet – heat sealed

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 6 mg/g Premix for medicated feeding stuff for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance: Ivermectin 6 mg/g

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff. Yellow-brown, free-flowing granules

4. PACKAGE SIZE

333 g

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Antiparasitic treatment for Pigs.

Treatment of nematode or arthropod infections due to:

Gastrointestinal roundworms

Ascaris suum (adults and L4) Hyostrongylus rubidus (adults and L4) Oesophagostomum spp. (adults and L4) Strongyloides ransomi (adults)*

Lungworms

Metastrongylus spp. (adults)

Lice Haematopinus suis

Mange mites

Sarcoptes scabiei var. suis

*Given to pregnant sows before farrowing, it effectively controls transmission via milk of *S. ransomi* to piglets.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

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

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.

The recommended dose level is 0.1 mg ivermectin/kg bodyweight fed daily for seven consecutive days. The appropriate inclusion rate of the the product, in grams per tonne of finished feed, can be calculated as follows:

100 x average bodyweight (kg)Premix inclusion rate =(g/tonne feed)6 x average daily feed intake (kg)

In order to avoid under or overdosing, pigs to be treated should be grouped by weight and the dose to be administered should be calculated based on the heaviest animal in the group.

Growing Pigs

The recommended dose level of 0.1 mg/kg bodyweight daily for seven days is obtained under most circumstances, for pigs up to 40 kg bodyweight, by including 333 g product in each metric tonne of final feed. The product should be thoroughly mixed in the finished feed and fed continuously as the only ration for seven consecutive days. In pigs weighing 40 kg liveweight and over, average daily feed consumption may fall below a feed intake of 5% of bodyweight where restricted feeding programmes are in use or where pigs are fed a ration high in protein. For pigs weighing 40 kg and over, include 400 g product in each metric tonne of final feed.

Adult Pigs

The recommended dose level for adult pigs weighing over 100 kg liveweight is achieved under most circumstances by thoroughly mixing 1.67 kg of the product in each metric tonne of swine ration. The resultant medicated feed is to be fed at the rate of 1 kg per 100 kg of bodyweight each day for seven consecutive days, as part of the individual ration. Where medicated feed is to be fed as part of the ration, it is recommended that the ivermectin medicated feed is fed first. After this is consumed, any remainder of the daily feed allocation should be provided. This should be repeated for seven consecutive days.

Alternatively, where dry feed intake can be accurately determined and all animals to be treated have similar bodyweight, the inclusion rate can be calculated using the previous formula to allow sole feeding of medicated feed.

RECOMMENDED TREATMENT PROGRAMME

Growing Pigs

Groups of growing pigs should be treated for seven consecutive days on transfer to clean quarters. Where an all-in all-out system is not possible, it is recommended that the in-feed parasite control programme should begin with treatment of all growing pigs already in the house.

Breeding animals: Breeding animals are treated by feeding medicated feed for seven consecutive days. At the time of initiating any parasite control programme, it is important to treat all animals in the herd. After the initial treatment, use the premix regularly as follows:

Sows: Treat 14-21 days prior to farrowing to minimize infection of piglets.

Gilts: Treat 14-21 days prior to breeding. Treat 14-21 days prior to farrowing.

Boars: Treat at least 2 times per year. Frequency of, and need for, treatments are dependent upon parasite exposure.

This product should be incorporated by licensed feed manufacturers only. The product can be incorporated in pelleted feed preconditioned with steam for up to10 seconds at a temperature not exceeding 65°C.

8. WITHDRAWAL PERIOD

Meat and offal: 12 days

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications

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

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

Special warnings for each target species

Exposure of treated pigs to infected animals, contaminated premises, soil or pasture may result in re-infestation and re-treatment may be necessary. 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. Because louse eggs are unaffected by ivermectin and may take up to three weeks to hatch, re-treatment may be necessary.

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.

Sick animals may have a reduced appetite and an altered drinking patterns and should, if necessary, individually monitored.

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.

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

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.

Adverse reactions

The effects of GABA agonists are increased by ivermectin

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

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other products.

Use during pregnancy, lactation or lay

The product can be administered to sows at any stage of pregnancy or lactation. This product can be used in breeding animals

Overdose

When included in the ration of pigs at levels up to 5 times the recommended dose of 0.1 mg ivermectin per kg bodyweight for 21 consecutive days (3 times the recommended treatment period), the product did not produce treatment related adverse reactions. No antidote has been identified.

10. EXPIRY DATE

MM/YYYY

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place Store in the original outer bag After incorporation into feed, use medicated feed within 8 weeks if meal and 4 weeks if pelleted.

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

Extremely dangerous to fish and aquatic life. Do not contaminate surface waters or ditches with the product or used container. Any unused veterinary medicinal product or waste materials 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.

To be supplied only on veterinary prescription.

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

ECO Animal Health Ltd. The Grange 100 High Street London N14 6BN United Kingdom

<u>Manufacturer for the batch release (EEA)</u>: Acme Drugs s.r.l.

Via Portella della Ginestra, 9/a, Zona Industriale Corte Tegge, 42025 CAVRIAGO (RE), Italy Tel: +39 0522.941919 E-mail: info@acmedrugs.com Manufacturer's authorisation number: 27/2016/V

Name and address of the manufacturer (UK): Cod Beck Blenders Limited. Cod Beck Estate, Dalton, Thirsk, North Yorkshire YO7 3HR United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13277/4020

17. MANUFACTURER'S BATCH NUMBER

Pack size: 333 g and 5 kg Not all pack sizes may be marketed.

OUTTER PACKAGE

5 kg foil bag – heat sealed

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

5 kg foil bag – heat sealed

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecomectin 6 mg/g Premix for medicated feeding stuff for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance: Ivermectin 6 mg/g

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff Yellow-brown, free-flowing granules

4. PACKAGE SIZE

5 kg

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Antiparasitic treatment for Pigs.

Treatment of nematode or arthropod infections due to:

Gastrointestinal roundworms

Ascaris suum (adults and L4) Hyostrongylus rubidus (adults and L4) Oesophagostomum spp. (adults and L4) Strongyloides ransomi (adults)*

Lungworms

Metastrongylus spp. (adults)

Lice Haematopinus suis

Mange mites

Sarcoptes scabiei var. suis

*Given to pregnant sows before farrowing, it effectively controls transmission via milk of *S. ransomi* to piglets.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

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

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.

The recommended dose level is 0.1 mg ivermectin/kg bodyweight fed daily for seven consecutive days. The appropriate inclusion rate of the the product, in grams per tonne of finished feed, can be calculated as follows:

100 x average bodyweight (kg)Premix inclusion rate =(g/tonne feed)6 x average daily feed intake (kg)

In order to avoid under or overdosing, pigs to be treated should be grouped by weight and the dose to be administered should be calculated based on the heaviest animal in the group.

Growing Pigs

The recommended dose level of 0.1 mg/kg bodyweight daily for seven days is obtained under most circumstances, for pigs up to 40 kg bodyweight, by including 333 g product in each metric tonne of final feed. The product should be thoroughly mixed in the finished feed and fed continuously as the only ration for seven consecutive days. In pigs weighing 40 kg liveweight and over, average daily feed consumption may fall below a feed intake of 5% of bodyweight where restricted feeding programmes are in use or where pigs are fed a ration high in protein. For pigs weighing 40 kg and over, include 400 g product in each metric tonne of final feed.

Adult Pigs

The recommended dose level for adult pigs weighing over 100 kg liveweight is achieved under most circumstances by thoroughly mixing 1.67 kg of the product in each metric tonne of swine ration. The resultant medicated feed is to be fed at the rate of 1 kg per 100 kg of bodyweight each day for seven consecutive days, as part of the individual ration. Where medicated feed is to be fed as part of the ration, it is recommended that the ivermectin medicated feed is fed first. After this is consumed, any remainder of the daily feed allocation should be provided. This should be repeated for seven consecutive days.

Alternatively, where dry feed intake can be accurately determined and all animals to be treated have similar bodyweight, the inclusion rate can be calculated using the previous formula to allow sole feeding of medicated feed.

RECOMMENDED TREATMENT PROGRAMME

Growing Pigs

Groups of growing pigs should be treated for seven consecutive days on transfer to clean quarters. Where an all-in all-out system is not possible, it is recommended that the in-feed parasite control programme should begin with treatment of all growing pigs already in the house.

Breeding animals: Breeding animals are treated by feeding medicated feed for seven consecutive days. At the time of initiating any parasite control programme, it is important to treat all animals in the herd. After the initial treatment, use the premix regularly as follows:

Sows: Treat 14-21 days prior to farrowing to minimize infection of piglets.

Gilts: Treat 14-21 days prior to breeding. Treat 14-21 days prior to farrowing.

Boars: Treat at least 2 times per year. Frequency of, and need for, treatments are dependent upon parasite exposure.

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 65°C.

8. WITHDRAWAL PERIOD

Meat and offal: 12 days

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications

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

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

Exposure of treated pigs to infected animals, contaminated premises, soil or pasture may result in re-infestation and re-treatment may be necessary. 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. Because louse eggs are unaffected by ivermectin and may take up to three weeks to hatch, re-treatment may be necessary.

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

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.

Adverse reactions

The effects of GABA agonists are increased by ivermectin

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

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other products.

Use during pregnancy, lactation or lay

The product can be administered to sows at any stage of pregnancy or lactation. This product can be used in breeding animals.

Overdose

When included in the ration of pigs at levels up to 5 times the recommended dose of 0.1 mg ivermectin per kg bodyweight for 21 consecutive days (3 times the recommended treatment period), the product did not produce treatment related adverse reactions. No antidote has been identified.

10. EXPIRY DATE

MM/YYYY

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place Store in the original outer bag After incorporation into feed, use medicated feed within 8 weeks if meal and 4 weeks if pelleted.

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

Extremely dangerous to fish and aquatic life. Do not contaminate surface waters or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

ECO Animal Health Ltd. The Grange 100 High Street London N14 6BN United Kingdom

<u>Manufacturer for the batch release (EEA)</u>: Acme Drugs s.r.l.

Via Portella della Ginestra, 9/a, Zona Industriale Corte Tegge, 42025 CAVRIAGO (RE), Italy Tel: +39 0522.941919 E-mail: info@acmedrugs.com Manufacturer's authorisation number: 27/2016/V

Name and address of the manufacturer (UK): Cod Beck Blenders Limited. Cod Beck Estate, Dalton, Thirsk, North Yorkshire YO7 3HR United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 13277/4020

17. MANUFACTURER'S BATCH NUMBER

Pack size: 333 g and 5 kg Not all pack sizes may be marketed.

Approved: 01 June 2023