ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET

{BAG 250 g, 500 g, 1000g, 2500g}

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release , if different

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, The Netherlands

2. Name of the veterinary medicinal product

Phenocillin 800 mg/g powder for use in drinking water for chickens

3. Statement of the active substance (s) and other ingredients

1 g powder contains:

Active substance:
Phenoxymethylpenicillin 800 mg
(corresponding to phenoxymethylpenicillin potassium 887 mg)

White or almost white powder.

4. Pharmaceutical form

Powder for use in drinking water..

5. Package size

250 g, 500 g, 1000 g, 2500g

6. Indication

For the treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens*. The disease must have been currently diagnosed in the flock before metaphylactic use.

7. Contraindications

Do not use in known cases of hypersensitivity to the active substance, other substances of the beta-lactam group or to any of the excipients.

8. Adverse reactions

Although no adverse reactions have been observed after the administration of the product, penicillins may cause vomiting, diarrhoea and alter gut flora by selecting resistant bacteria.

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}

9. Target species

Chickens

10. Dosage for each species, route and method of administration

13.5 – 20 mg phenoxymethylpenicillin per kg body weight per day, corresponding to 17 – 25 mg of the product per kg body weight per day, for 5 days.

Method of administration: oral use, dissolve in drinking water and use within 12 hours. The maximum solubility is 100 g product per litre drinking water.

The following calculation may be used to determine the quantity in grams of the product to be added to 1000 litres of water:

$$\frac{\text{mg product/kg body weight/day} \times \text{mean body weight of individual animals (kg)} \times \text{number of animals}}{\text{Total water consumption (litre) of the group to be treated on the previous day}} = \text{mg product /litre} = \text{g product/ 1000 l water}$$

To calculate correctly the amount of powder required, the use of calibrated weighing equipment is recommended. Taking into account that sick animals may drink less, it is recommended to start therapy with the highest authorised dose, to compensate for a possible lower intake of medicated water.

To ensure correct dosage, the body weight of the animals should be determined as accurately as possible to avoid under dosing.

No other source of drinking water should be available during the medication period. In cases of altered drinking water consumption in chickens, the concentration should be adjusted so that the recommended dosage is achieved. After the end of the treatment period, the water supply system should be cleaned to avoid subsequent intake of sub-therapeutic amounts of the active substance.

11. Advice on correct administration

None

12. Withdrawal period(s)

Withdrawal periods:
Meat and offal: 2 days.
Eggs: zero days.

13. Special storage precautions

This veterinary medicinal product does not require any special storage conditions.

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.

14. Special warnings

Special precautions for use in animals:
Use of the product should be based on susceptibility testing of bacteria isolated from the animals on the farm. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. The product should not be used to compensate for poor hygiene and management of the farm houses. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to phenoxymethylpenicillin and may decrease the effectiveness of treatment with other penicillins, due to the potential for cross-resistance. Official, national and regional antimicrobial policies should be taken into account when the product is used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins, such as phenoxymethylpenicillin, may cause hypersensitivity (allergy) following inhalation, ingestion or skin contact. Hypersensitivity to phenoxymethylpenicillin may lead to cross-sensitivity to other penicillins and cephalosporins, and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Persons handling this product should avoid inhalation of any dust and contact with skin. Wear protective clothing, impervious gloves and either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with a filter to EN143 when mixing and handling the product.

Hands and exposed skin should be washed thoroughly after use.

Lay:
Studies in laboratory animals and humans have not produced any evidence of effects on reproductive function or foetal development.

Interaction with other medicinal products and other forms of interaction:
This veterinary medicinal product should not be combined with bacteriostatic antibiotics.

Overdose (symptoms, emergency procedures, antidotes):
Phenoxymethylpenicillin has a high therapeutic ratio. The administration of medicated drinking water at two and five times the recommended therapeutic dose for twice the recommended duration of treatment, did not reveal any adverse effects. In some individuals, administration of five times the recommended therapeutic dose for twice the recommended duration of treatment led to an increase in water consumption, a decrease in feed intake and watery faeces.

Incompatibilities:
Do not mix with other veterinary medicinal products.
Contact of penicillin containing solutions with metals and the use of metal systems for their administration is known to adversely influence penicillin stability. Therefore the use of such systems should be avoided and they should not be used for the storage of solutions.

15. Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the label was last approved

December 2020

17. Other information

Pack sizes: 100 g, 10 x 100 g, 250 g, 500 g, 1000 g and 2500 g.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. 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.

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

EXP: {month/year}
Once opened, use by _____

Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution or reconstitution according to directions: 12 hours.

21. Marketing authorisation number(s)

Vm 16849/4054

22. Manufacturer’s batch number

Lot: {number}

PARTICULARS TO APPEAR ON:

Carton for 10 x 100 g bags

Label for 100 g bags (10 x 100 g)

Booklet label for 100 g bags (1 x 100 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Phenocillin 800 mg/g powder for use in drinking water for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

1 g powder contains:

Active substance:
Phenoxymethylpenicillin 800 mg
(corresponding to phenoxymethylpenicillin potassium 887 mg)

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

100 g, 10 x 100 g

5. TARGET SPECIES

Chickens

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use, dissolve in drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 2 days.
Eggs: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP: {month/year}
Once opened, use by _____
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution or reconstitution according to directions: 12 hours.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC 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.

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.
[this information will not be included on the immediate package for 10 x 100 g]

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4054

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Phenocillin 800 mg/g powder for use in drinking water for chickens

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

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Phenocillin 800 mg/g powder for use in drinking water for chickens

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

1 g powder contains:

Active substance:
Phenoxymethylpenicillin 800 mg
(corresponding to phenoxymethylpenicillin potassium 887 mg)
White or almost white powder

4. INDICATION(S)

For the treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens*. The disease must have been currently diagnosed in the flock before metaphylactic use.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance, other substances of the beta-lactam group or to any of the excipients.

6. ADVERSE REACTIONS

Although no adverse reactions have been observed after the administration of the product, penicillins may cause vomiting, diarrhoea and alter gut flora by selecting resistant bacteria.

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. Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Chickens.

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

13.5 – 20 mg phenoxymethylpenicillin per kg body weight per day, corresponding to 17 – 25 mg of the product per kg body weight per day, for 5 days.

Method of administration: oral use, dissolve in drinking water and use within 12 hours. The maximum solubility is 100 g product per litre drinking water.

The following calculation may be used to determine the quantity in grams of the product to be added to 1000 litres of water:

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To calculate correctly the amount of powder required, the use of calibrated weighing equipment is recommended. Taking into account that sick animals may drink less, it is recommended to start therapy with the highest authorised dose, to compensate for a possible lower intake of medicated water.

To ensure correct dosage, the body weight of the animals should be determined as accurately as possible to avoid under dosing.

No other source of drinking water should be available during the medication period. In cases of altered drinking water consumption in chickens, the concentration should be adjusted so that the recommended dosage is achieved. After the end of the treatment period, the water supply system should be cleaned to avoid subsequent intake of sub-therapeutic amounts of the active substance.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD(S)

Meat and offal: 2 days.
Eggs: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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: 3 months.
Shelf life after dilution or reconstitution according to directions: 12 hours.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
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13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

Pack sizes: 100 g, 10 x100 g, 250 g, 500 g, 1000 g and 2500 g.
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 31 March 2021