1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:
Phenoxymethylpenicillin 800 mg
(equivalent to phenoxymethylpenicillin potassium 887 mg)

Excipients:

Qualitative composition of excipients and other constituents
Potassium dihydrogen phosphate
Silica colloidal anhydrous

White or almost white powder.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

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.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal 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 veterinary medicinal product should not be used to compensate for poor hygiene and management of the farm houses.

Use of the veterinary medicinal 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 veterinary medicinal 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. People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.
2. Handle this veterinary medicinal 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 immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Persons handling this veterinary medicinal product should avoid inhalation of any dust and contact with skin. Personal protective equipment consisting of 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 should be worn when mixing and handling the veterinary medicinal product.

Hands and exposed skin should be washed thoroughly after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Undetermined frequency (cannot be estimated from the available data):	Diarrhoea, Disorder of gastrointestinal flora[a], Vomiting

[a] Alter gut flora by selecting resistant bacteria.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

This veterinary medicinal product should not be combined with bacteriostatic antibiotics.

3.9 Administration routes and dosage

In drinking water use.

Dissolve in drinking water and use within 12 hours. The maximum solubility is 100 g product per litre drinking water.

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

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{mg veterinary medicinal product/kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{mg veterinary medicinal product per litre of drinking water} = \text{g veterinary medicinal product/ 1000 l water}$$

To calculate correctly the amount of powder required, the use of suitably calibrated measuring 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 a correct dosage, body weight should be determined as accurately as possible.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :
QJ01CE02.

4.2 Pharmacodynamics

Phenoxymethylpenicillin is a narrow-spectrum penicillin with activity mainly against gram-positive

bacteria.

Phenoxymethylpenicillin, as all penicillins, exerts a bactericidal action, on bacteria during the stage of active multiplication. It forms an irreversible binding to penicillin-binding proteins (PBPs), enzymes that facilitate the formation of cross-links of peptidoglycan chains in the synthesis of the bacterial cell wall. This results in abnormal cell growth and cytolysis of the cell.

Phenoxymethylpenicillin is an acid-stable derivative of benzylpenicillin and has a largely comparable spectrum of activity.

Development of resistance is mainly based on the formation of beta-lactamase, an enzyme that breaks open the beta-lactam ring rendering the antibiotic ineffective. Cross-resistance exists between phenoxymethylpenicillin and other beta-lactam antibiotics.

Minimum Inhibitory Concentrations (MICs) of phenoxymethylpenicillin were determined against *Clostridium perfringens* isolates from clinical cases of necrotic enteritis in chickens during 1998 and 1999. The MIC for *C. perfringens* isolated from faeces, liver and caecum samples were < 0.01 to 0.05 µg/ml.

4.3 Pharmacokinetics

The most important advantage of phenoxymethylpenicillin in comparison with penicillin G is that it is more stable in an acid environment and it is therefore better absorbed from the gastrointestinal tract.

Following oral use, phenoxymethylpenicillin for the most part escapes decomposition by gastric juices, as it is stable at a low pH.

Phenoxymethylpenicillin is well distributed over most of the tissues, leading to a high concentration in the kidneys and the liver. Phenoxymethylpenicillin is partially decomposed in the gastrointestinal tract. A small portion of the absorbed amount is metabolised in the body. For the most part, phenoxymethylpenicillin is excreted in unaltered active form in urine and faeces.

Following a single administration of the veterinary medicinal product in chickens at a dose of 15 mg of phenoxymethylpenicillin potassium / kg body weight by oral gavage, maximum plasma concentrations of 0.40 ± 0.15 mg / l were achieved within 1.7 ± 1.0 hours after administration. Phenoxymethylpenicillin is well absorbed and has an absolute bioavailability of 69%.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any 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.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution or reconstitution according to directions: 12 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Bags consisting of the following materials: on the outside a polyethylene terephtalate layer, inside layers of aluminium and polyamide and an inner layer of polyethylene. Pack sizes are 100 g, 10x 100 g, 250 g, 500 g and 1000 g.

Bags consisting of the following materials: on the outside a paper layer, inside layers of polyethylene and aluminium and an inner layer of polyethylene. Pack sizes are 1000 g and 2500 g.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10989/065/001

8. DATE OF FIRST AUTHORISATION

22/01/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

12/06/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).