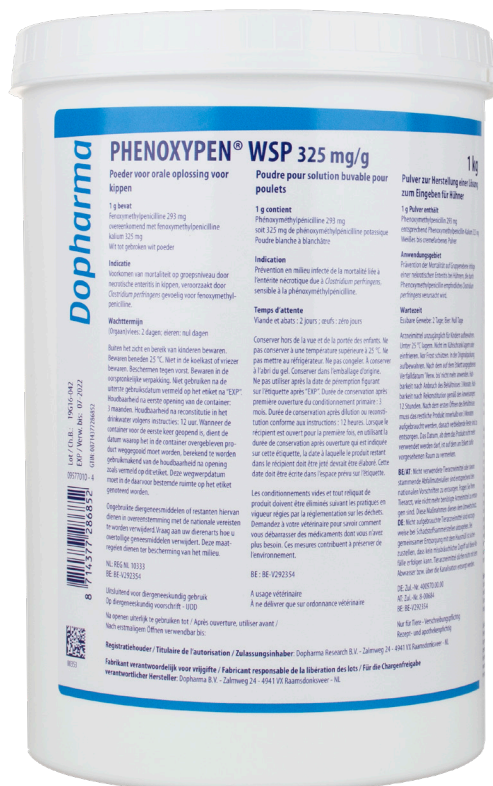


Phenoxyphen® WSP

Phenoxyethylpenicillin



Characteristics

- New treatment option for common streptococcal infections in pigs
- Narrow spectrum penicillin: phenoxyethylpenicillin or ‘penicillin V’
- Effective and targeted solution of *Streptococcus suis* infections
- Gram-positive spectrum induces less resistance and disturbance in the gram-negative microbiome
- Developed for drinking water treatment: highly water-soluble and acid-stable

Phenoxyphen[®] WSP

Marketing authorisation holder

Dopharma Research B.V.

Packaging

Jar 1 kg
Bucket 5 kg

Pharmaceutical form

Powder for oral use

Composition

Per gram:
phenoxymethylpenicillin 293 mg
equivalent to potassium phenoxymethyl-
penicillin 325 mg

Target species

Chicken, pig

Indications

Chicken: Prevention of mortality at a group level from necrotic enteritis in chickens caused by *Clostridium perfringens*.

Pig: Treatment and metaphylaxis of infections caused by *Streptococcus suis*. The presence of the disease in the group must be established before the product is used.

Route of administration and dosage

Orally, in drinking water

Chicken: 13.5 - 20 mg phenoxymethylpenicillin per kg body weight per day, corresponding with 46 - 68 mg product per kg body weight per day, for 5 days.

Pig: 15 mg phenoxymethylpenicillin per kg of body weight per day, corresponding with 51 mg of the product per kg of body weight per day, for 5 days.

The following calculation should be made to determine the quantity in gram of the product to be added in 1000 litres of water:

$$\frac{\text{mg product/ kg body weight/day} \times \text{mean body weight of individual animals (kg)} \times \text{number of animals}}{\text{total water consumption of the house (litres) at the previous day}} = \text{mg product/l} = \text{g product/1000 l water}$$

Medicated drinking water should be refreshed every 12 hours.

The maximum solubility is 250 g of the product per litre of drinking water.

Withdrawal period

Chicken: meat and offal: 2 days
eggs: 0 days

Pig: meat and offal: 4 days

Contraindications

Hypersensitivity to the active substance.

Adverse reactions

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

Special warnings

Special warnings for each target species

Chicken: the administration of the product may lead to an increase in medicated water consumption.

Cross-resistance has been shown between phenoxymethylpenicillin and other beta-lactam antibiotics. Use of the product should be carefully considered when susceptibility testing has shown resistance to beta-lactam antibiotics because its effectiveness may be reduced.

Special precautions for use in animals

Pigs with severe clinical symptoms, such as septicæmic shock, should be treated parenterally.

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the product should be in accordance with official, national and regional antimicrobial policies. The product should not be used to compensate for poor hygiene and management of the chicken houses.

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

Phenoxymethylpenicillin may cause hypersensitivity reactions after injection, inhalation, oral ingestion, skin or eye contact. Hypersensitivity to phenoxymethylpenicillin may lead to cross-sensitivity to other penicillins and cephalosporins, and vice versa. Allergic reactions caused by these substances can sometimes be serious. People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the veterinary medicinal product. Handle this product with great care to avoid exposure, taking all recommended precautions. 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 EN 143 when mixing and handling the product. Wash hands immediately after handling the product. In case of accidental ingestion or serious symptoms of hypersensitivity reactions such as skin rash following exposure, swelling of the face, lips or eyes or difficulty with

breathing, seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian. Laboratory studies in animals and studies in humans have not produced any evidence of effects on reproductive function or foetotoxic effects.

Interactions with other medicinal products and other forms of interaction

Do not combine with bacteriostatic antibiotics.

Overdose (symptoms, emergency procedures, antidotes)

Phenoxymethylpenicillin has a high therapeutic index.

Pig: the administration of the medicated drinking water up to five times the recommended therapeutic dose for three times the recommended duration of treatment was well tolerated. However, at five times the recommended therapeutic dose a reduction in water intake and temporary redness of the skin were observed.

Chicken: the administration of the 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 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, such systems should be avoided and they should not be used for the storage of solutions.

Storage conditions and shelf life

Store below 25 °C.

Do not refrigerate or freeze. Protect from frost. Store in the original package.

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.

Shelf life after first opening of the immediate packaging: 3 months.

Shelf life after reconstitution in drinking water according to directions: 12 hours.

To be supplied only on veterinary prescription. For the complete product information read the SPC.