

Phenoxyphen[®] WSP 325 mg/g

Phenoxyethylpenicillin (penicillin V) 325 mg/g



Healthy livestock

 **Dopharma**

Necrotic enteritis

Necrotic enteritis is a highly important disease in poultry.

- The clinical form of the disease causes high mortality.^{1,4}
- Subclinical disease results in great economic losses^{2,4} due to:
 - increased mortality⁴;
 - decreased growth rate^{2,4};
 - decreased uniformity of the flock²;
 - impaired feed conversion rate^{1,4};
 - increased carcass condemnations.^{2,4}
- Impairment of the feed conversion rate does not only occur during the infection, but also after.⁴
- There are many predisposing factors that play a role and are difficult to control:
 - changes to the gut;
 - changes to the immune system;
 - disruption of microbiota;
 - proliferation of pathogenic *C. perfringens* strains.³
- Commercial vaccines are not available.

Effective treatment of necrotic enteritis halts the disease and therefore prevents any further losses.

References

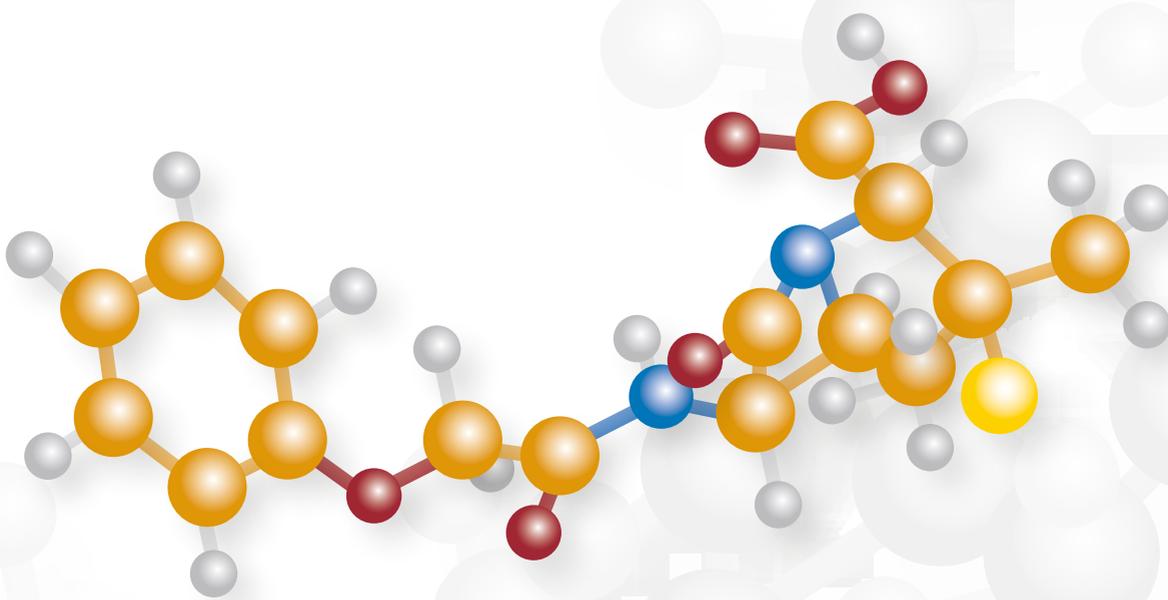
1. Ducatelle, R., Timmermont, L., Mot, D., Antonissen, G., Haesebrouck, F. and van Immerseel, F. (2013) Recent findings on nutritional strategies for the control of necrotic enteritis. *WPSA Proceedings 19th European symposium on poultry nutrition*.
2. Lee, K.W., Lillehoj, H.S., Jeong, W., Jeong, H.Y. and An, D.J. (2011) Avian necrotic enteritis: Experimental models, host immunity, pathogenesis, risk factors, and vaccine development. *Poultry sci* 90: 1381-1390.
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4. Paiva, D. and McElroy, A. (2014) Necrotic enteritis: Applications for the poultry industry. *J Appl Poult Res* 23: 557-566.



Phenoxymethylpenicillin

Phenoxymethylpenicillin is an excellent treatment option for chickens with necrotic enteritis.

- Responsible and rational* use of antibiotics.
 - Phenoxymethylpenicillin is a narrow spectrum antibiotic.
 - The risk for public health is low or limited.¹
 - There is no influence on the presence of ESBL and AmpC-beta-lactamase producing organisms.⁴
 - Dopharma conducted efficacy studies with excellent results.
 - In these studies it was shown that phenoxymethylpenicillin is as effective as ampicillin for the treatment of necrotic enteritis.
- Safety
 - Phenoxymethylpenicillin is a molecule with a high safety margin.²
- Acid stability
 - Phenoxymethylpenicillin is acid stable. Absorption from the gastro-intestinal tract is therefore better when compared to other narrow spectrum penicillins such as benzylpenicillin.^{2,3}



References

1. European medicines agency - EMA (2014) Answers to the requests of scientific advice on the impact on public health and animal health of the use of antibiotics in animals. EMA381884/2014.
2. Phenoxypen specific product characteristics.
3. Plumb, D.C. (2011) Plumb's veterinary drug handbook, 7th Edition. Wiley-Blackwell, Ames, Iowa. Penicillin G, page 789; Penicillin V potassium, page 793.
4. Werkgroep veterinair antibioticumgebruik - WVAB (2012) Smal- versus breedspectrum antibiotica en eerste, tweede en derde keus op basis van Gezondheidsraad-advies. English translation available upon request.

* Information on responsible and reliable use can be found on the website www.dopharma.com.

Phenoxyphen[®] WSP



Characteristics

- Packaged in a robust and re-sealable jar containing 1 kg.
- Perfect solubility.
 - Up to 250 grams of Phenoxyphen[®] 325 mg/g can be dissolved rapidly and completely in one litre of water.
- Withdrawal periods:
 - Meat and offal: 2 days.
 - Eggs: 0 days.

Phenoxyphen[®] WSP

Marketing authorisation holder

Dopharma Research B.V.

Packaging

Can 1 kg

Jar 1 kg

Pharmaceutical form

Powder for oral use

Composition

Per gram:

phenoxymethylpenicillin 293 mg

equivalent to potassium phenoxymethylpenicillin 325 mg

Target species

Chicken

Indications

Chicken:

Prevention of mortality at a group level from necrotic enteritis in chickens caused by *Clostridium perfringens* susceptible to phenoxymethylpenicillin.

Route of administration and dosage

Chicken:

Orally, in drinking water

13.5 - 20 mg phenoxymethylpenicillin per kg bodyweight per day (corresponding with 46 - 68 mg product per kg bodyweight per day), for 5 days.

The following calculation should be made to determine the quantity in gram of the product to be added in 1 000 litres of water:

mg product/ kg body- weight/day	mean bodyweight x of individual animals (kg)	number x of animals
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total water consumption of the house (litres) at the previous day

= mg product/l x 1 000 = g product/1 000 l water

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

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

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

Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from chickens that have already died on the farm. 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. 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 to the physician.

People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the product. In case of development of hypersensitivity symptoms following exposure to the product, all further contact with the product (and other medicines containing other penicillins or cephalosporins) should be avoided.

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.

Use during lay

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

Interactions with other medicinal products and other forms of interaction

Do not combine with bacteriostatic antibiotics.

Overdosage (symptoms, emergency procedures, antidotes)

Phenoxymethylpenicillin has a high therapeutic index. 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 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.

Store in the original package.

Do not refrigerate or freeze.

Protect from frost.

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.

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