

FLOCAL 100 (FLORFENICOL 10% w/v ORAL SOLUTION)

FLOCAL 100 (FLORFENICOL 10% w/v ORAL SOLUTION) appears to be a light yellow color, clear solution.

Composition

Each ml contains
Florfenicol 100mg

Pharmacodynamic

Florfenicol is a broad-spectrum synthetic antibiotic in the phenicol group that is active against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibition of protein synthesis at the ribosomal level and is bacteriostatic. However, bactericidal activity has been demonstrated in-vitro against *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* when florfenicol is present at concentrations above the MIC for up to 12 hours.

In-vitro testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory diseases in pigs, including *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*. Acquired resistance to florfenicol is associated with several genes, including FloR which encodes an efflux pump.

Pharmacokinetic

After administration to pigs by gavage at 15 mg/kg under experimental conditions, absorption of florfenicol was variable but peak serum concentrations of approximately 5 µg/ml were reached approximately 2 hours after dosing. The terminal half-life was between 2 and 3 hours. When pigs were given free access, for 5 days, to water medicated with the veterinary medicinal product at a concentration of 100 mg florfenicol per litre of water, serum concentrations of florfenicol exceeded 1 µg/ml for the entire 5 day treatment period except for a couple of short excursions below 1 µg/mL. After absorption and distribution, florfenicol is extensively metabolised by pigs and rapidly eliminated, primarily in urine. After parenteral dosing of florfenicol to pigs, it has been shown that lung concentrations are similar to serum concentrations.

Indications

In pigs:

Treatment and metaphylaxis at the group level where clinical signs are present of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol. The presence of the disease should be established in the herd before initiating metaphylactic treatment.

Recommended Dosage

In drinking water use.

10 mg florfenicol per kg bodyweight per day in drinking water for 5 consecutive days. Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily amount of the veterinary product should be calculated according to the following formula:

$$\frac{\text{X ml veterinary product/ kg b.w./day}}{\text{Mean daily water consumption (litre) per animal}} \times \text{Mean body weight (kg) of animals to be treated} = \text{X ml veterinary product per litre drinking water}$$

Instruction for Use

The appropriate quantity of medicated water should be prepared based on the daily water consumption. To ensure a correct dosage body weight should be determined as accurately as possible. In order to avoid under- and over-dosing, treated animals should be divided into groups of similar bodyweight and the dose should be calculated for each group individually.

For Bulk Tank:

To treat pigs drinking 10% of their bodyweight, at the dose of 10 mg/kg: add the florfenicol solution to the drinking water in the bulk tank. Use one bottle (1L) of florfenicol solution for every 1000 L of water or use one barrel (5L) of florfenicol solution for every 5000 L of water and mix thoroughly.

For Proportioner:

To treat 5,000 kg of pigs, drinking 10% of their bodyweight, at the dose rate of 10 mg/kg:

1. Empty the content of one bottle/barrel of florfenicol solution in the proportioner and dilute with drinking water as follows:

Bottle/Barrel	Amount of drinking water
1 L	100 L
5 L	500 L

2. Mix thoroughly.
3. Set the proportioner on 10%
4. Turn on the proportioner.

Warning: Solutions with concentrations higher than 1.2 g of florfenicol per litre may precipitate. Do not use the product with chlorinated water. The uptake of medicated water depends on several factors including the clinical state of the animals and local conditions such as ambient temperature and humidity. In order to obtain the correct dosage water uptake has to be monitored and the concentration of florfenicol has to be adjusted accordingly. If however it is not possible to obtain sufficient uptake of medicated water animals should be treated parenterally.

Contraindication

Do not use in boars intended for breeding purposes. Studies in rats have revealed evidence of potential adverse effects on the male reproductive system. Do not use in case of hypersensitivity to the active substance or to any of the excipient.

Warning and Precautions

Special warnings

The treated pigs should be placed under special observation. On each of the five days of treatment, unmedicated drinking water should not be given until the full daily amount of medicated drinking water has been ingested by pigs.

If there are no signs of improvement after three days of treatment, the diagnosis should be reviewed and, if necessary, the treatment changed.

Special precautions for use in animals

The veterinary medicinal product should be used in conjunction with susceptibility testing.

FLOCAL 100 (FLORFENICOL 10% w/v ORAL SOLUTION)

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the florfenicol.

Official and local antimicrobial policies should be taken into account when the product is used.

Treatment should not exceed 5 days.

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

This product may cause irritation of the skin and eyes.

Florfenicol may cause adverse effects on male reproductive systems, such as shrinking of the testes.

Contact of the neat product, or the medicated drinking water, with skin and eyes should be avoided.

Personal protective equipment consisting of protective gloves, coverall and safety glasses should be worn when handling and mixing the product. Do not smoke, eat or drink when handling the product or mixing the medicated drinking water.

In case of accidental spillage into eyes, wash them immediately with water. In case of contact with skin, wash the affected area immediately and remove any contaminated clothing.

This product may cause hypersensitivity (allergic) reactions in some people.

People with known hypersensitivity to florfenicol or propylene glycol should avoid contact with the veterinary medicinal product.

If you develop symptoms following exposure, such as skin rash, seek medical advice and take the package leaflet or the label with you.

Special precautions for the protection of the environment

This product should not be allowed to enter surface waters as it has harmful effects on aquatic organisms.

Interactions with Other Medicaments

No data available.

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

The use is not recommended during pregnancy and lactation.

Laboratory studies in animals have not produced any evidence of embryotoxic or foetotoxic effects.

Side effects

Pigs:

Very common (>1 animal / 10 animals treated):	Diarrhoea ¹ Localized oedema ^{1,2}
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Decreased drinking, unusual stool colour ³ Constipation Rectal prolapse ⁴

1. Peri-anal and rectal erythema/oedema which may affect approximately 40% of the animals. Transient.

2. Not application site

3. Dark brown faeces.

4. Resolving without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent to either the marketing authorisation holder or the national competent authority.

Overdose and Treatment

After administration at 3 times the recommended dose a decrease in weight gain, food and water consumption, peri-anal erythema and oedema and modification of some haematological and biochemical parameters indicative of dehydration may be observed.

Withdrawal Period (s)

Meat and offal: 20 days.

Storage

Store below 30°C. Protect from heat and sunlight exposure.

Keep out of reach of children/ Jauhkan dari kanak-kanak.

Any unused product or packaging should be disposed of in accordance with local and national legislation.

Shelf life as packaged for Sale: 3 years.

Shelf life after first opening: 30 days.

Shelf life after dilution: 24 hours.

Packaging

1L

Product Registration Holder/Distributed By

GNC Agritech Sdn Bhd

24 Jalan Industri Cherok Tokun3, Taman Tokun Jaya,
14000 Bukit Mertajam, Pulau Pinang, Malaysia.

Manufacturer

NAM PHARMA SDN. BHD.

5, Lebuhr Perusahaan Klebang 11,
Taman Perindustrian Antarabangsa IGB,
31200 Chemor, Perak, Malaysia.

Date of revision: 02-06-2026