NAFLOR ORAL SOLUTION
(Florfenicol)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NAFLOR ORAL SOLUTION.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Florfenicol ……. 100mg

3. PHARMACEUTICAL FORM

Oral Solution.

4. CLINICAL INFORMATION

4.1. Target species

Poultry Chickens.

4.2. Indications for use specifying the target species

Chickens: For the treatment of infections caused by florfenicol-susceptible strains of E. coli.

4.3. Contraindications

Do not use in boars intended for breeding.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4. Special warnings for each target species

On each of the five days of treatment, non-medicated drinking water should only be given after the entire volume of medicated water required for the day of treatment has been consumed. If clinical signs do not improve after three days of treatment, evaluate the diagnosis and change treatment if necessary. In case of insufficient intake of medicated water, treat animals parenterally.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Special precautions for safe use in target species: The use of this veterinary medicinal product should be based on the results of susceptibility testing of bacteria isolated from the animal. Official, national and regional antimicrobial policies should be taken into account when using this veterinary medicinal product. Use of this veterinary medicinal product deviating from the instructions given in the summary of product characteristics may

increase the prevalence of bacteria resistant to florfenicol. The duration of treatment should not exceed 5 days. In case of insufficient intake of medicated water, treat animals parenterally.

Special precautions to be taken by the person administering the product to animals:

People with known hypersensitivity to florfenicol or polyethylene glycols should avoid contact with this veterinary medicinal product. In case of accidental skin contact, rinse the affected area with water. Wear gloves when handling this veterinary medicinal product. When using this veterinary medicinal product for the treatment of poultry, bird excrement (manure) must not be released into the environment from the start of use until the 15th day after stopping use.

Special precautions for environmental protection

Not applicable.

4.6. Adverse reactions (frequency and seriousness)

Side effects in chickens are unknown.
It is important to report adverse reactions. This allows for continuous monitoring of the safety of veterinary medicinal products. Reports should preferably be sent via a veterinarian, either to the marketing authorisation holder or to the national competent authority via the national reporting system. See the package leaflet for the relevant contact details.

4.7. Use during pregnancy and lactation or lay

For laying birds: Do not use in birds during the laying period.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

Data not available.

4.9. Dosage and administration route

For use in drinking water.

Chickens: 20 mg florfenicol per kg body weight per day (equivalent to 0.2 ml of this veterinary medicinal product/kg body weight/day). Duration of treatment: 5 consecutive days.

During treatment, medicated water should be the only source of drinking water available to animals.
To avoid underdosing, body weight should be determined as accurately as possible. The intake of medicated water depends on the clinical condition of the animal and the ambient temperature. In order to obtain the correct dosage, it may be necessary to adjust the concentration of this veterinary medicinal product accordingly, taking into account the actual amount of water consumed and the body weight of the animals to be treated, using the following formula:

(x ml of this veterinary medicinal product per kg body weight per day) * (average body weight of animals to be treated (kg)) / (average water consumption (l) per day per animal) = x ml of this veterinary medicinal product per litre of drinking water

To avoid precipitation, the concentration of florfenicol in water should not exceed 1 gram per liter. The medicated drinking water should be changed every 24 hours.
This veterinary medicinal product should be added to the drinking water and mixed thoroughly until the veterinary medicinal product is completely dissolved. A water supply should be easily accessible to ensure that the animals to be treated have sufficient water intake. After the end of the treatment period, the water supply system must be thoroughly cleaned to prevent incomplete intake of the active substance.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of overdose, reduced body weight gain, decreased food and water consumption, redness and swelling in the perianal area, as well as changes in some haematological and biochemical parameters indicating dehydration may be observed.

4.11 Specific restrictions on use and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products to reduce the risk of development of resistance

Not applicable.

4.12. Withdrawal period:

For meat and offal: 8 days.
Do not use in birds whose eggs are used or intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: **QJ01BA90**

5.1. Pharmacodynamics properties

Florfenicol is a broad-spectrum synthetic antibiotic active against many Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at the ribosomal level and is bacteriostatic. Florfenicol is a derivative of thiamphenicol in which the hydroxyl group has been replaced by fluorine. Laboratory tests have confirmed the activity of florfenicol against pathogenic bacteria most commonly isolated from birds, including *Escherichia coli*, including *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*. Resistance to florfenicol is mainly due to the presence of single (e.g. floR) or multiple (e.g. AcrAB-TolC) efflux pumps. The genes responsible for these mechanisms are encoded in genetic elements such as plasmids, transposons or gene cassettes. Acquired resistance to florfenicol, mainly encoded by chromosomal genes floR and cfr. In recent years, a transmissible plasmid encoding florfenicol resistance has been discovered.

Minimum inhibitory concentration (MIC) breakpoints for veterinary pathogens (CLSI, 2018): *Actinobacillus pleuropneumoniae, Pasteurella multocida*: susceptible: ≤ 2 µg/ml, intermediate susceptible: 4 µg/ml, resistant: ≥ 8 µg/ml.

5.2 Pharmacokinetic information

Chickens: After a single oral dose of 30 mg florfenicol per kg body weight, peak serum concentrations of 3.20 µg/ml were reached within 63.1 minutes. The oral bioavailability was 55.3%. Florfenicol is well distributed in the body. The highest tissue concentrations were found in the kidneys (4.1 – 4.7 µg/g), lungs (2.8 – 2.9 µg/g), muscles (2.0 – 2.4 µg/g), bile (1.6 – 2.75 µg/g), intestines (approximately 2.0 µg/g), heart muscles (1.7 – 2.1 µg/g), liver (1.5 – 1.8 µg/g) and spleen (1.3 – 1.5 µg/g).

6. PHARMACEUTICAL INFORMATION

6.1 Excipients:

Macrogol 300 (Polyethylene glycol)

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use within 28 days, do not store.
Shelf life after dilution according to instructions: 24 hours.

6.4. Special precautions for storage

Store below 25°C.
Do not refrigerate or freeze.
Protect from light and moisture.
Shake well before use.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

The product is available in various pack sizes:

- For 100ml Whiter PP bottles with Sealed with screw tight caps
- For 1L and 500mL HDPE Bottles with induction-sealed caps
- For 2.5 L: HDPE can with induction-sealed caps

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Waste materials derived from the use of such products
Medicinal products should not be disposed of via wastewater or household waste.
Use return systems for unused veterinary medicinal products or waste materials derived from such products, in accordance with local requirements and national collection systems applicable to the veterinary medicinal product concerned.
Treated animals should be kept in shelters throughout the treatment period and their droppings should be collected and NOT used for soil fertilization.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 049514

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 22-07-2008

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.
136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.