

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR Drinking Water Concentrate for Swine, 23 mg/mL, Concentrate for Oral Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Florfenicol	23 mg/mL
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For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for oral solution.

Clear, colourless to yellow, slightly viscous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Swine.

4.2 Indications for use, specifying the target species

In swine:

Treatment and prevention 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 preventative treatment.

4.3 Contraindications

Do not use in boars intended for breeding purposes.

Do not administer in cases of previous allergic reactions to florfenicol.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals:

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

Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to florfenicol. Treatment should not exceed 5 days.

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

People with known hypersensitivity to polyethylene glycols should avoid contact with the veterinary medicinal product.

In case of accidental spillage onto skin, rinse with water.

Other precautions:

Manure from treated pigs should be stored for 1 month prior to spreading and incorporating into land.

4.6 Adverse reactions (frequency and seriousness)

A slight reduction of water consumption by the animals, dark brown faeces and constipation may be observed during treatment.

Commonly observed adverse effects are diarrhoea and/or peri-anal and rectal erythema/oedema which may affect approximately 40% of the animals.

These effects are transient. In a few of the affected animals, prolapse of the rectum, that resolves without treatment, may be observed.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not revealed any evidence of potential embryotoxic or foetotoxic effects of florfenicol.

The safety of the veterinary medicinal product in sows has not been established during pregnancy and lactation. The use is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

10 mg florfenicol per kg bodyweight per day in drinking water for 5 consecutive days.

The amount of the florfenicol concentrate solution (NDWC) can be calculated based on the Total Body Weight of herd to be treated (TBW) and the Total Water Consumption of the herd in 24 hr (TWC) with the following formula:

$$\text{NDWC (L)} = \frac{10 \times \text{TBW (kg)}}{23 \times \text{TWC (L)}} \text{ per 1000L of medicated water in the tank}$$

If a proportioner set at P% is used, then the formula is

$$\text{NDWC (L)} = \frac{10 \times \text{TBW (kg)}}{23 \times \text{TWC (L)}} \times \frac{1}{\text{P\%}} \text{ per 10L of pre-diluted medicated water in the proportioner}$$

Dilute the calculated volume of NDWC with water to a total volume of 10L in the proportioner. To avoid florfenicol precipitation risk in the proportioner the following values should be avoided $0.5 < \text{NDWC}/10\text{L} < 5.2$. When the calculation yields a value within this interval the proportioner set up (P%) should be changed.

The appropriate quantity of medicated water or pre-diluted medicated water should be prepared based on the daily water consumption.

Specific examples are given below:

FOR BULK TANK: To treat pigs drinking 10% of their bodyweight, at the dose of 10 mg/kg: add the florfenicol concentrate solution to the drinking water in the bulk tank. Use one bottle (2.17 L) of florfenicol concentrate solution for every 500 L of water and mix thoroughly. This corresponds to a 100 mg/L drinking water concentration.

FOR PROPORTIONER: Two convenient proportioner settings for the use of florfenicol in the drinking water are 10% and 1%.

A. Ten percent setting:

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 (2.17 L) of florfenicol concentrate solution in the proportioner.
2. Dilute to 50 L with drinking water.
3. Mix thoroughly.
4. Set the proportioner on 10%.
5. Turn on the proportioner.

B. One percent setting:

To treat 5,000 kg of pigs, drinking 8% of their body weight, at the dose rate of 10 mg/kg:

1. Empty the content of one bottle of florfenicol concentrate solution in the proportioner.
2. Dilute to 4 L with drinking water.
3. Mix thoroughly.
4. Set the proportioner on 1%.
5. Turn on the proportioner.

Warning: Solutions with concentrations comprised between 1.2 g and 12 g of florfenicol per litre precipitate.

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.

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

In case of overdosing, 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.

4.11 Withdrawal Period(s)

Meat and offal: 20 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Amphenicols

ATC vet code: QJO1BA

5.1 Pharmacodynamic properties

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*.

5.2 Pharmacokinetic properties

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 Nuflor Drinking Water Concentrate 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene glycol.

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
 Shelf-life after dilution or reconstitution according to directions (in-use): 24 hours
 Do not use the veterinary medicinal product for more than 5 hours with proportioners, if galvanised piping is used.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

Pack Sizes: Bottle of 2.17L;
Containers: Flat oval, opaque high density polyethylene (HDPE) bottle;
Closures: HDPE screw cap with a tamper proof ring and polyethylene, polyester and aluminium seal;
Dosing Devices: Not applicable.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
 Magna Drive
 Magna Business Park
 Citywest Road
 Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/239/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27th February 2007

10 DATE OF REVISION OF THE TEXT

November 2012