SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NIFENCOL 100 mg/mL Solution for use in Drinking Water for Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Florfenicol 100 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in Drinking Water.
Clear, colourless to yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

In pigs:
Treatment and metaphylaxis 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 metaphylaxis.

4.3 Contraindications

Do not use in boars intended for breeding purposes.
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

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.
In case of insufficient water intake, animals should be treated parenterally.

4.5 Special precautions for use

Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal.
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 hypersensitivity. People with known hypersensitivity to florfenicol or any of the excipients should avoid contact with the veterinary medicinal product.
Contact of the product or the medicated drinking water with skin and eyes should be avoided.
Personal protective equipment consisting of homologated protective gloves, coverall and safety glasses should be worn when handling and mixing the veterinary medicinal product.
In case of accidental spillage onto eyes, wash them immediately with water. In case of contact with skin, wash immediately the affected area and take the contaminated clothes off.
If you develop symptoms following exposure such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not smoke, eat or drink when handling the product or mixing the medicated drinking water.

Other precautions

In order to prevent any adverse effects on algae and possible contamination of groundwater, manure from treated pigs must not be spread onto land without dilution with manure from untreated pigs. Manure from treated pigs must be diluted with at least 5 times the weight of manure from untreated pigs before it can be spread onto arable 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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not revealed any evidence of potential embryotoxic or foetotoxic effect 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

In drinking water use.
10 mg florfenicol per kg bodyweight per day in drinking water (equivalent to 0.1 mL of the veterinary medicinal product/kg bw) 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:

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

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 (500 ml) of florfenicol solution for every 500 L of water, 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 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
500 ml	50 L
1L	100 L
5L	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.

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

Meat and offal: 20 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antimicrobials for systemic use, amphenicols
ATCvet code: QJ01BA90

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.*

The MIC_{90} values of florfenicol against *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* strains isolated in Czech Republic (2015-2016) and United States and Canada (2011-2015), were determined as 0.5 µg/ml, respectively. For *A. pleuropneumoniae* and *P. multocida*, the CLSI breakpoint of resistance for swine respiratory disease is 8 µg/ml (2013).
Acquired resistance to florfenicol is associated with several genes, including FloR which encodes an efflux pump.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 300

6.2 Major 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: 18 months
Shelf-life after first opening the immediate packaging: 3 months
Shelf life after dilution according to directions: 24 hours

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Pack sizes: Bottles of 500 ml and 1L and barrels of 5L.
Containers: White high-density polyethylene (HDPE) bottles and barrels
Closures: HDPE screw cap with induction sealing.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

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

7. MARKETING AUTHORISATION HOLDER

Vetpharma Animal Health, S.L.
Gran Via Carles III, 98, 7ª
08028 Barcelona
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 32509/4017

9. DATE OF FIRST AUTHORISATION

27 June 2014

10. DATE OF REVISION OF THE TEXT

December 2024

Gavin Hall
Approved: 01 December 2024