LABELLING AND PACKAGE LEAFLET

LABEL-LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Bottles of 500 ml and 1L, Barrels of 5L

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder
VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 BARCELONA
SPAIN

Manufacturer responsible for batch release:
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
SPAIN

Distributed by:

2. Name of the veterinary medicinal product

NIFENCOL 100 mg/mL Solution for use in Drinking Water for Pigs [AT, BE, BG, ES, FR, IT HU, IE, NL, PT, UK]

Nifencol 100 mg/ml solution for use in drinking water for pigs [PL]
Florfenicol

3. Statement of the active substance (s) and other ingredients

Each ml contains:

Active substance:
Florfenicol 100 mg

Clear, colourless to yellow solution.

4. Pharmaceutical form

Solution for use in drinking water.

5. Package size

500 ml
1L
5L

6. Indication(s)

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.

7. 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.

8. Adverse reactions

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).

If you notice any side **effects,** even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Pigs

10. Dosage for each species, route(s) and method of administration

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:

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

11. Advice on correct administration

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.

12. Withdrawal period(s)

Withdrawal period: Meat and offal: 20 days.

13. Special storage precautions

Do not store above 25ºC.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

14. Special warning(s)

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.

Special precautions for use in animals
Use of the product should be used 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.

Pregnancy and lactation
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.

Interaction with other medicinal products and other forms of interaction
No data available.

Overdose (symptoms, emergency procedures, antidotes)
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.

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

15. Special precautions for the disposal of unused products or waste materials, if any

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.

16. Date on which the package leaflet was last approved

17. Other information

Pack sizes: Bottles of 500 ml and 1L and barrels of 5L
Not all pack sizes may be marketed.

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP
Shelf life after dilution according to directions: 24 hours
Shelf-life after first opening the container: 3 months
Once opened, use by ……

21. Marketing authorisation number(s)

22. Manufacturer's batch number

Batch