

**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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**3. STATEMENT OF THE ACTIVE SUBSTANCE 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. INDICATIONS

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, ROUTES AND METHODS 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:

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

## 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 PERIODS**

Withdrawal period: Meat and offal: 20 days.

## **13. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C.

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 WARNINGS**

### 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, perianal 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**

November 2022

### **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**

Vm 32509/4017

**22. MANUFACTURER’S BATCH NUMBER**

Batch

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE**

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

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 ml contains:

**Active substance:**

Florfenicol 100 mg

**3. PHARMACEUTICAL FORM**

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

**4. PACKAGE SIZE**

500 ml bottle  
1L bottle  
5L barrel

**5. TARGET SPECIES**

Pig

**6. INDICATIONS**

In pigs:

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 preventive treatment.

**7. METHOD AND ROUTES OF ADMINISTRATION**

To be administered in drinking water.

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:

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

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

5. 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

6. Mix thoroughly.
7. Set the proportioner on 10%
8. 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.



## **8. WITHDRAWAL PERIOD**

Withdrawal period: Meat and offal: 20 days.

## **9. SPECIAL WARNINGS, IF NECESSARY**

### 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.

### Special precautions for use in animals

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

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

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

In case of accidental spillage onto skin rinse with water. In case of contact with eyes, rinse immediately with copious amounts of water.

Personal protective goggles should be worn when handling the veterinary medicinal product.

### 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.

### 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.

### Interaction with other medicinal products and other forms of interaction

No data available.

### Overdose

In case of overdosing, a decrease in weight gain, food and water consumption, perianal 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.

## **10. EXPIRY DATE**

### **EXP**

Shelf life after dilution or reconstitution according to directions: 24 hours

Shelf-life after first opening the immediate packaging: 3 months

Once broached/opened, use by .....

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

## **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

## **13. 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.

## **14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER**

Vm 32509/4017

**17. MANUFACTURER'S BATCH NUMBER**

Batch

**18. OTHER INFORMATION**

**Contraindications**

Do not use in boars intended for breeding purposes.  
Do not use in case of hypersensitivity to the active substance or to the excipient.

**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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

**Date on which the package leaflet was last approved:**

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

Approved 17 November 2022

