

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Florolab 100 mg/ml solution for use in drinking water for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Florfenicol 100 mg

### Excipient:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Macrogol 300	

Clear, colourless to yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs.

### 3.2 Indications for use for each target species

In pigs:

Treatment and metaphylaxis 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 metaphylactic treatment.

### 3.3 Contraindications

Do not use in boars intended for breeding purposes. Studies in rats have revealed evidence of potential adverse effects on the male reproductive system.

Do not use in cases of hypersensitivity to the active substance or to any of the excipient.

### 3.4 Special warnings

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.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

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:

This product may cause irritation of the skin and eyes.

Florfenicol may cause adverse events on male reproductive systems, such as shrinking of the testes. Contact of the neat product, or the medicated drinking water, with skin and eyes should be avoided. Personal protective equipment consisting of protective gloves, coverall and safety glasses should be worn when handling and mixing the product.

Do not smoke, eat or drink when handling the product or mixing the medicated drinking water.

In case of accidental spillage into eyes, wash them immediately with water. In case of contact with skin, wash the affected area immediately and remove any contaminated clothing.

This product may cause hypersensitivity (allergic) reactions in some people.

People with known hypersensitivity to florfenicol or propylene glycol should avoid contact with the veterinary medicinal product.

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.

Special precautions for the protection of the environment:

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

### 3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Diarrhoea <sup>1</sup> Localized oedema <sup>1,2</sup>
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Decreased drinking, unusual stool colour <sup>3</sup> Constipation Rectal prolapse <sup>4</sup>

1. Peri-anal and rectal erythema/oedema which may affect approximately 40% of the animals. Transient.
2. Not application site.
3. Dark brown faeces.
4. Resolving without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

The use is not recommended during pregnancy and lactation.  
Laboratory studies in animals have not produced any evidence of embryotoxic or foetotoxic effects.

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

No data available.

### 3.9 Administration routes and dosage

In drinking water use.

Recommended dose, 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 concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{ml veterinary medicinal product/kg body weight per day}}{\text{average daily water intake (l/animal)}} \times \text{average body weight (kg) of animals to be treated} = \text{ml veterinary medicinal product per litre of drinking water}$$

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 body weight 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 (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 5000 kg of 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
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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After administration at 3 times the recommended dose 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.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 Withdrawal periods**

Meat and offal: 20 days.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code:**

QJ01BA90

### **4.2 Pharmacodynamics**

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<sub>90</sub> 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.

### **4.3 Pharmacokinetics**

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.

### **4.4 Environmental properties**

Florfenicol is toxic to cyanobacteria.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

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

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing other substances used in drinking water.

## **5.2 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

## **5.3 Special precautions for storage**

Do not store above 25°C.

## **5.4 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.

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

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Dangerous to aquatic primary producers (cyanobacteria). Do not contaminate surface waters or ditches with the product or used container.

## **6. NAME OF MARKETING AUTHORISATION HOLDER**

Labiana Life Sciences, S.A.

## **7. MARKETING AUTHORISATION NUMBER(S)**

VPA10402/003/001

## **8. DATE OF FIRST AUTHORISATION**

23/08/2019

## **9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

29/01/2026

## **10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).