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

{NATURE/TYPE}

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

Marketing authorisation holder
Labiana Life Sciences S.A.
Calle Venus 26
E-08228 Terrassa
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

Or

LABIANA LIFE SCIENCES, S.A.
C/ Venus, 26, Pol. Ind. Can Parellada
08228 - Terrassa
SPAIN

2. Name of the veterinary medicinal product

Floralab 100 mg/ml solution for use in drinking water for pigs
Florfenicol

3. Statement of the active substances and other ingredients

Each ml contains:

Active substance:
Florfenicol 100 mg

4. Pharmaceutical form

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

5. Package size

500 ml bottle
1L bottle
5L barrel

6. Indications

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.

7. Contraindications

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

8. Adverse reactions

A slight reduction of water consumption by the animals, dark brown faeces and constipation may be observed during treatment.
Very 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 reactions)
- 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 and method of administration

In drinking water use.
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:

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

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 (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:

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.

12. Withdrawal period

Withdrawal period: Meat and offal: 20 days.

13. Special storage precautions

Do not store above 25°C.

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.

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:
This product may cause irritation of the skin and eyes.
Florfenicol may cause adverse effects 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 and take the package leaflet or the label with you.

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

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 (symptoms, emergency procedures, 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.

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

16. Date on which the label 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 {month/year}>

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 ……
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.

21. Marketing authorisation number(s)

Vm 32112/4002

22. Manufacturer's batch number

Batch

Approved: 17/12/21