LABELLING AND PACKAGE LEAFLET

LABEL-LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORTEK 100 mg/ml Solution for use in drinking water for pigs [ES]
K-FLOR 100 mg/ml Solution for use in drinking water for pigs [UK, PL, HU, PT, RO]
Florfenicol

2. STATEMENT OF ACTIVE SUBSTANCES

Each 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

Pigs

6. INDICATION(S)

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 preventive treatment.

7. METHOD AND ROUTE(S) 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:

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

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:
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.

Warnings:
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 WARNING(S), 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
Florfenicol and polyethylene glycol may cause hypersensitivity (allergy).
People with known hypersensitivity to florfenicol or polyethylene glycols should avoid contact with the veterinary medicinal product.
This product may cause skin and eye irritation.
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.
Medical advice should be sought if irritation persists.

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 (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.

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 opened, use by …..

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

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. The product should not be allowed to enter surface water as it has harmful effects on aquatic organisms.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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. Administration by a veterinary surgeon or under their direct responsibility.

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 AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and 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(S)

17. MANUFACTURER'S BATCH NUMBER

Batch

18. OTHER INFORMATION

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 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, very commonly.
Diarrhoea and/or peri-anal and rectal erythema/oedema may occur very commonly (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.
Neurological signs and death can be observed in the animals treated on rare occasions. In that case withdraw the treatment immediately.

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 package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}

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