

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

K-FLOR 100 mg/ml solution for use in drinking water for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Florfenicol 100 mg

Excipients:

Qualitative composition of excipients and other constituents

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:

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 equipment consisting of goggles should be worn when handling the veterinary medicinal product.

If you develop symptoms following exposure such as irritation, you should seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

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.

3.6 Adverse events

Pigs

Very common (>1 animal / 10 animals treated):	Decreased drinking ¹ Unusual stool colouration ² , constipation, diarrhoea ³ , perianal and rectal oedema ³ Erythema ^{3,4}
Rare (1 to 10 animals / 10,000 animals treated):	Neurological signs ⁵ Death

¹Slight.

² Dark brown faeces.

³It 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.

⁴Perianal and rectal.

⁵In that case withdraw the treatment immediately.

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 package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Studies in laboratory animals have not produced any evidence of potential embryotoxic or foetotoxic effects 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.

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.

Dosage: 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 product should be calculated according to the following formula:

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

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 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

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* for florfenicol.

The latest registered data of florfenicol in the CLSI is from the year 2013 (CLSI VET01-A4 with the supplement VET01-S3-2013) indicating the following data: $\leq 2 \mu\text{g} / \text{ml}$ (S), $4 \mu\text{g} / \text{ml}$ (I) and $\geq 8 \mu\text{g} / \text{ml}$ (R).

In addition, the report published by the Medicines Agency of the Czech Republic (Státní veterinární správa) entitled *Národní program sledování rezistencí k antimikrobikům u veterinárně významných patogenů*, Informační bulletin č. 4/2017, shows that in studies conducted on infected *P. multocida* pigs during 2015 and 2016, for a total of 72 isolates, almost 100% of the strains were sensitive to florfenicol.

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 $\mu\text{g}/\text{ml}$ 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 $\mu\text{g}/\text{ml}$ for the entire 5 day treatment period except for a couple of short excursions below 1 $\mu\text{g}/\text{mL}$.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

This veterinary medicinal product must not be administered using drinking water containing chlorine as the active substance florfenicol degrades in the presence of this biocidal active substance.

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

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

White high-density polyethylene containers closed with a HDPE screw cap with induction sealling.

Pack sizes:

Bottle of 500 ml

Bottle of 1 L

Barrel of 5 L 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.

The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for fish and other aquatic organisms.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Karizoo S.A

7. MARKETING AUTHORISATION NUMBER

Vm 31223/4003

8. DATE OF FIRST AUTHORISATION

27 June 2014

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

March 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved 30 March 2026