

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains:

Active substance:

Florfenicol 100 mg

Excipients:

Qualitative composition of excipients and other constituents

Macrogol 300

Clear, colourless to yellow solution.

3. PACKAGE SIZE

500 ml bottle

1L bottle

5L barrel

4. TARGET SPECIES

Pigs

5. INDICATIONS FOR USE

Indications for use

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.

6. CONTRAINDICATIONS

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.

7. SPECIAL WARNINGS

Special warnings

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.

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.

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.

Interactions 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.

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.

8. ADVERSE EVENTS

Adverse events

Pigs

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

¹Slight.

² Dark brown faeces.

³ It 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.

⁵ In that case withdraw the treatment immediately.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system at: Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

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:

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

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 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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 20 days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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

This 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 31223/4003

Pack sizes

Bottle of 500 ml

Bottle of 1 L

Barrel of 5 L

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

17. CONTACT DETAILS

Contact details

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

Local representatives and contact details to report suspected adverse reactions:

Vetsonic (UK) Ltd
Riccald Drive,
York Road Business Park,
Malton, YO17 6YE,
United Kingdom
Tel: 01653 695333
E-mail: ellen.stephenson@vetsonic.com or amanda@vetsonic.com

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

18. OTHER INFORMATION

Other information

POM-V

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

EXP

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

Shelf life after dilution according to directions: 24 hours

Once opened, use by

21. BATCH NUMBER

Lot {number}

Gavin Hall

Approved 30 March 2026