[Version 9.1,11/2024]

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:
Active substance:
Florfenicol ……..100 mg
Clear, colourless to yellow solution.

3. Target species

Pigs.

4. Indications for use

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.

5. 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 excipients.

6. 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:
This veterinary medicinal 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 veterinary medicinal 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 show the package leaflet 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.

Pregnancy and lactation:
The safety of the veterinary medicinal product in sows has not been established during pregnancy and lactation. Laboratory studies have not produced any evidence of potential embryotoxic or foetotoxic effect of florfenicol. Use only according to the benefit-risk assessment by the responsible veterinarian.
Fertility:
Do not use in boars intended intending for breeding (see section *Contraindications*).

Overdose:
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.
Special restrictions for use and special conditions for use:

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

7. Adverse events

Pigs:

Very common (>1 animal/10 animals treated):	Diarrhoea[2] Erythema[1,2] Oedema[1,2]
Undetermined frequency (cannot be estimated from the available data):	Reduced water intake Constipation[3] Rectal prolapse[4]

[1] Peri-anal and rectal.
[2] These effects are transient and may affect approximately 40% of the animals.
[3] With dark brown faeces
[4] It resolves without treatment

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

In drinking water use.
Administer 10 mg florfenicol/kg b.w./day 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:

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

9. 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 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 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.

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 this is not possible, animals should be treated parenterally.

10. Withdrawal periods

Meat and offal: 20 days.

11. 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.
Shelf-life after first opening the immediate packaging: 3 months.
Shelf life after dilution according to directions: 24 hours.

12. 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.
Dangerous to aquatic primary producers (cyanobacteria). Do not contaminate surface waters or ditches with the product or used container.
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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Bottles of 1 L and barrels of 5 L.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
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