1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYCOFLOR 200 mg/mL, solution for use in drinking water for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substances:
Florfenicol .....200 mg

Excipients:

Qualitative composition of excipients and other constituents
Dimethylacetamide
Polysorbate 80
Glycerol formal

Yellow clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

Treatment and metaphylaxis at the group level where clinical signs of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* are present. The presence of the disease in the group should be established before initiating metaphylactic treatment.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of resistance to the active substance.
Do not use in boars intended for breeding purposes. Studies in rats have revealed evidence of potential adverse effects on the male reproductive system.
See section 3.7

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.

In case of insufficient water intake, animals should be treated parenterally.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol and may decrease the effectiveness of treatment with amphenicols due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal product may cause hypersensitivity reactions.

People with known hypersensitivity to florfenicol, dimethylacetamide or propylene glycol should avoid contact with the veterinary medicinal product.

This veterinary medicinal product contains dimethylacetamide, which has been shown to have the potential to affect the development of unborn children.

Pregnant women and women of child-bearing age should avoid working with this veterinary medicinal product.

Contact of the veterinary medicinal product or the medicated drinking water with skin and eyes including hand-to-eye-contact 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 veterinary medicinal 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.

If you develop symptoms following exposure such as skin rash, seek medical advice and take the package leaflet or the label with you.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs.

Common (1 to 10 animals / 100 animals treated):	Erythema (peri-anal) Decreased drinking[1] Constipation[1], Abnormal stool colouration[1,2], Soft stool[1], Rectal prolapse[3]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Neurological signs[4] Death[4]

1 transient, short-term and do not affect the general condition of the animals
2 dark brown
3 retroceding without treatment
4 the medication should be withdrawn immediately and unmedicated water provided.

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

Do not use during pregnancy and lactation.

The veterinary medicinal product contains dimethylacetamide, which is considered to be a reproductive toxicant.

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.

The recommended dose is 10 mg florfenicol per kg body weight daily (corresponding to 5 mL of the veterinary medicinal product / 100 kg b.w.) given for 5 consecutive days.

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.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

To ensure a correct dosage body weight should be determined as accurately as possible.

The appropriate quantity of medicated water should be prepared based on the daily water intake.

The veterinary medicinal product should be added to the drinking water by thorough stirring until the veterinary medicinal product is completely dissolved. Sufficient access to the water supply should be available for the animals to be treated to ensure adequate water intake. No other source of drinking water

should be available during the medication period. In free range husbandry systems animals should be housed during treatment.

The water supply should be cleaned appropriately after the end of the medication period to avoid intake of sub-therapeutic amounts of active substance.

FOR PROPORTIONER:

1. Introduce the amount of the veterinary medicinal product in the proportioner and dilute with drinking water as follows (examples):

Weight of animals	Amount of veterinary medicinal product	Amount of water (corr. to 1 mg florfenicol/mL of water)
500 kg	25 mL	5 L
1000 kg	50 mL	10 L
10,000 kg	500 mL	100 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 precipitate.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdosing, a decrease in weight gain, water intake, peri-anal 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: 23 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ01BA90.

4.2 Pharmacodynamics

Florfenicol is a synthetic broad-spectrum antibiotic that has activity against a wide range of Gram-positive and Gram-negative bacterial species. It acts by inhibiting bacterial protein synthesis, and is generally considered to have a bacteriostatic action.

Florfenicol is a derivative of thiamphenicol, in which the hydroxyl group has been replaced with fluorine. This makes it effective against chloramphenicol resistant, acetyl transferase producing bacteria.

Laboratory tests have confirmed the activity of florfenicol against *Actinobacillus pleuropnemoniae and Pasteurella multocida* in swine.

Resistance to florfenicol mainly comes from the presence of specific (e.g. florR) or multi-substance (e.g. AcrAB-TolC) efflux pumps. The genes corresponding to these mechanisms are coded on genetic elements such as plasmids, transposons or gene cassettes. Cross resistance with chloramphenicol is possible. Amphenicols select for the chloramphenicol-florfenicol resistant gene (*cfr*), conferring multiresistance phenotypes to phenicols, lincosamides, oxazolidinones, pleuromutilins, and streptogramin A in MRSA and enterococci.

The following Minimal Inhibitory Concentrations (MIC) have been determined for florfenicol in European isolates collected from pigs with respiratory tract infections between 2007 and 2019. For florfenicol in swine respiratory disease, CLSI (2018) breakpoints are: susceptible ≤ 2 µg/mL, intermediate 4 µg/mL and resistant ≥ 8 µg/mL.

Target species	Bacterial pathogen	MIC_{50} (µg/mL)	MIC_{90} (µg/mL)
Pigs	*Actinobacillus pleuropneumoniae*	0.5	0.5
	Pasteurella multocida	0.5	0.5

4.3 Pharmacokinetics

Florfenicol is well distributed to most body tissues. The maximum concentration is reached in kidney, liver, bladder, lung and in intestines. Approximately 50% of florfenicol is excreted from the organism unchanged. The remaining part is excreted as a metabolite (mainly florfenicol amine).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

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

Do not use the product with chlorinated water.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
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

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

1 litre containers: white, opaque high density polyethylene bottles sealed by induction and with polyethylene screw-on cap.

5 litre container: white, opaque high density polyethylene barrels sealed by induction and with polyethylene screw-on cap.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

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.
The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for aquatic organisms (cyanobacteria), including groundwater organisms.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

S.P. VETERINARIA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10790/007/001

8. DATE OF FIRST AUTHORISATION

29/04/2016

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

10/02/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).