SUMMARY OF PRODUCT CHARACTERISTICS

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:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in drinking water.
Yellow clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the 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.

4.3 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 4.7

4.4 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.

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

4.5 Special precautions for use

Special precautions for use in animals
Use of the 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 product should be in accordance with official, national and regional antimicrobial policies.

Use of the 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.

Do not use the product with chlorinated water.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause hypersensitivity (allergy).

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

This 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 product.

Contact of the 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 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.

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.

4.6 Adverse reactions (frequency and seriousness)

A slight reduction of water intake by the animals, dark brown faeces and constipation may be observed commonly during treatment.

Peri-anal erythema and soft faeces may commonly occur after using the veterinary medicinal product. These effects are transient, short-term and do not affect the general condition of the animals.

Prolapse of the rectum that resolves without treatment may be observed commonly.

Neurological signs and death may be observed very rarely in treated animals. If observed, the medication should be withdrawn immediately and unmedicated water provided.

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).

4.7 Use during pregnancy, lactation or lay

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

Do not use during pregnancy and lactation.

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

4.8 Interaction with other medicinal products and other forms of interaction

No data available

4.9 Amounts to be administered and administration route

In drinking water use.

The recommended dose is 10 mg florfenicol per kg body weight daily (corresponding to 5 ml of the 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 the animals to be treated, the exact daily amount of the veterinary product should be calculated according to the following formula:

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

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

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 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 Mycoflor 200 mg/ml oral solution in the proportioner and dilute with drinking water as follows (examples):

Weight of animals	Amount of 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal: 23 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antimicrobials for systemic use, amphenicols.
ATCvet code: QJ01BA90

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethylacetamide
Polysorbate 80
Glycerol formal

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

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

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

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

SP Veterinaria, S.A.
Ctra Reus Vinyols km 4.1
43330 Riudoms
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 36967/4003

9. DATE OF FIRST AUTHORISATION

06 May 2016

10. DATE OF REVISION OF THE TEXT

March 2022

Approved: 15 March 2022