1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MYCOFLOR, 300 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains
Active substance:
Florfenicol 300 mg

Excipients:
N-methyl pyrrolidone 200 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for Injection.
Clear, light yellow to yellow solution.

4. CLINICAL PARTICULARS

4.1 Target Species
Cattle, pigs.

4.2 Indications for use, specifying the target species

Cattle: Treatment of respiratory tract infections due to strains of *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni* susceptible to florfenicol.

Pigs: Treatment of acute outbreaks of swine respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

4.3 Contraindications

Do not use in adult bulls and boars intended for breeding purposes.
Do not use in piglets of less than 2 kg.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer intravenously.
Do not use in known cases of resistance to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use
Special precautions for use in animals
The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.
The stopper must be cleaned before removing each dose. Use a dry, sterile syringe and needle.

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 other antimicrobials, due to the potential for cross-resistance.

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

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid direct contact with skin, mouth and eyes. If eye exposure occurs, flush eyes immediately with clean water. If skin exposure occurs, wash the affected area with clean water. If accidental ingestion occurs, rinse the mouth with plenty of water and seek medical advice immediately.
Wash hands after use.
People with known hypersensitivity to florfenicol should avoid contact with the veterinary medicinal product.
Do not smoke, eat or drink while handling this product.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection

4.6 Adverse reactions (frequency and seriousness)
Cattle:
A decrease in food consumption and transient softening of the faeces may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.
Administration of the product by the intramuscular route may cause inflammatory lesions at injection site which persist for 14 days.
On very rare occasions, anaphylactic reactions were observed

Pigs:
Commonly observed adverse effects are transient diarrhoea and/or peri-anal and rectal erythema/oedema which may affect 50% of the animals. These effects can be observed for one week.
Transient swelling lasting up to 5 days may be observed at the site of injection. Inflammatory lesions at the injection site may be seen up to 28 days.
Under field conditions, approximately 30% of treated pigs may present with pyrexia (40°C) associated with either moderate depression or moderate dyspnoea a week or more after administration of the second dose.
The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy and lactation
The safety of the veterinary medicinal product has not been established in cattle and pigs during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only

according to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction
No data available.

4.9 Amounts to be administered and administration route
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The vial cannot be broached more than 25 times.

Cattle: IM injection of 20 mg/kg BW (1ml/15kg) into the neck muscle twice 48 hours apart. The volume administered per injection site should not exceed 10 ml. Subsequent injections must be given at different sites.

Pigs: IM injection of 15 mg/kg BW (1 ml/20 kg) into the neck muscle, twice, 48 hour apart. The volume administered per injection site should not exceed 3 ml. Subsequent injections must be given at different sites.

It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours after the second injection. If clinical signs of respiratory disease persist 48 hours after the last injection, treatment should be changed using another formulation or another antibiotic and continued until clinical signs have resolved.
Ensure that the injection site is clean before administration of the product

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

In swine after administration of 3 times the recommended dose or more a reduction in feeding, hydration and weight gain has been observed. After administration of 5 times the recommended dose or more vomiting has also been noted.

4.11 Withdrawal periods

Cattle:
Meat and offal: 34 days
Milk: Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 18 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacoterapeutic group: Antibacterials for systemic use, amphenicols
Florfenicol ATC vet code: QJ01BA90

5.1 Pharmacodynamic properties
Florfenicol is a synthetic broad spectrum antibiotic effective against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at the ribosomal level and is bacteriostatic.

However, bactericidal activity has been demonstrated in vitro against most common bacterial pathogens involved in respiratory disease : *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Actinobacillus pleuropneumoniae.*

Acquired resistance to florfenicol is mediated by efflux pump resistance associated with a *flo gene*. Cross resistance with chloramphenicol can occur.

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

Species	Bacterial pathogen	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)
Cattle	*Mannheimia haemolytica*	0.5 - 1	1
	Pasteurella multocida	0.5	0.5 - 1
	Histophilus somni	0.25	0.25
Pigs	*Actinobacillus pleuropneumonia*	0.25 – 0.5	0.5
	Pasteurella multocida	0.5	0.5

5.2 Pharmacokinetic particulars

Cattle:
Intramuscular administration at the recommended dose of 20 mg/kg maintains efficacious blood levels in cattle for 48 hours. Maximum mean serum concentration (C_{max}) of 4.02 µg/ml occurs at 7.0 hours (T_{max}) after dosing.
The mean serum concentration 24 hours after dosing was 1.57 µg/ml. The terminal half-life was 15.1 hours.

Pigs:
After intramuscular administration of the recommended dose of 15 mg/kg, maximum serum concentration of 2.48 µg/ml is reached after 2.0 hours and the concentrations deplete with a terminal half-life of 14.9 hours.
Serum concentrations drop below 1 µg/ml, the MIC90 for the target porcine pathogens, 12-24 hours following IM administration. Florfenicol concentrations achieved in lung tissue reflect plasma concentration, with a lung:plasma concentration ratio of approximately 1. After administration to pigs by the intramuscular route, florfenicol is rapidly excreted, primarily in urine. The florfenicol is extensively metabolised.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
N-Methylpyrrolidone
Glycerol formal

6.2 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: 28 days.

6.4 Special precautions for storage
This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging
Vial sizes: 100 and 250 ml
-Colourless Type II glass vials closed with bromobutyl rubber closures and an aluminium cap.
- Polypropylene vials closed with bromobutyl rubber closures and an aluminium cap.

Vials are individually packed in carton box.

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 SA
Ctra Reus Vinyols Km 4.1
Riudoms (43330)
España

8. MARKETING AUTHORISATION NUMBER

VPA10790/004/001

9. DATE OF THE FIRST AUTHORISATION

21/12/2011

10. DATE OF REVISION OF THE TEXT

December 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE