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 substances:
Florfenicol ..... 300 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
N-methyl pyrrolidone	200 mg
Glycerol formal	

Clear, light yellow to yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each 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.

3.3 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 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of fetotoxic 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

Special precautions for the protection of the environment:

The use of this veterinary medicinal product may pose a risk for terrestrial plants, cyanobacteria and groundwater organisms.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Reduced food intake[1]; Loose stool[1,2]; Injection site lesion[3], Anaphylaxis.

[1] Quick and complete recovery upon termination of treatment.
[2] Transient.
[3] Persists for 14 days.

Pigs:

Very common (>1 animal / 10 animals treated):	Pyrexia[1,2]; Depression[3], Dyspnoea[3]; Diarrhoea[4], Oedema[4,5], Local erythema[4,5].
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site swelling[6], Injection site lesion[7].

[1] 40ºC.
[2] associated with either moderate depression or moderate dyspnoea a week or more after administration of the second dose.
[3] Moderate.
[4] Can be observed for one week (transient).
[5] (Peri)anal and rectal.
[6] Transient, observed up to 5 days.
[7] Observed up to 28 days.

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 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.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

Pigs and cattle: Intramuscular use (**i.m.**)
To ensure a correct dosage body weight should be determined as accurately as possible. The vial cannot be broached more than 25 times.

Cattle: **i.m.** injection of 20 mg/kg BW (1 ml/15 kg) 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: **i.m.** 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.

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

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.

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

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

Pigs:
Meat and offal: 18 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ01BA90.

4.2 Pharmacodynamics

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

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

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: 28 days.

5.3 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.

5.4 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.

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 fish and other aquatic organisms.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

S.P. VETERINARIA, SA.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10790/004/001

8. DATE OF FIRST AUTHORISATION

21/12/2011

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

01/05/2026

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).