Florfenicol solution for injection for cattle, sheep and pigs

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains active substance Florfenicol 300 mg.

INDICATIONS FOR USE

- For the treatment of respiratory tract infections caused by strains of Actinobacillus pleuropneumoniae, Pasteurella multocida and Flavobacterium tooxigenicum.
- For treatment of Actinobacillus suis and Porphyromonas paludum.
- For treatment of Pasteurella multocida.

ADVERSE REACTIONS

- Breastfeeding: The product has not been established in sheep under 2 weeks of age.
- Cattle: Treatment of acute outbreaks of swine respiratory disease caused by strains of Actinobacillus pleuropneumoniae and Pasteurella multocida susceptible to florfenicol.
- Sheep: Treatment of acute outbreaks of swine respiratory disease caused by strains of Actinobacillus pleuropneumoniae and Pasteurella multocida susceptible to florfenicol.

SPECIAL PRECAUTIONS FOR USE

- This medicinal product does not contain any antimicrobial preservative.
- Special precautions for use in animals: The safety of the product has not been established in sheep under 2 weeks of age. Do not use in pigs of less than 2 kg. The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.

ADVERSE REACTIONS (FREQUENCY AND SERIOUSNESS)

- Cattle: A decrease in food consumption and transient serofusion 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 and subcutaneous routes may cause inflammatory lesions at injection site which may persist up to 28 days.
- Sheep: Inflammatory lesions at the injection site may be seen up to 28 days. The volume administered per injection site should not exceed 10 ml.

AMOUNT TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Cattle: Intramuscular route: 20 mg of florfenicol/kg bodyweight (equivalent to 1 ml of the product/15 kg bodyweight) to be administered twice 48 hours apart using a 16 gauge needle. Subcutaneous route: 40 mg of florfenicol/kg bodyweight (equivalent to 2 ml of the product/15 kg bodyweight) to be administered once using a 15 gauge needle. The dose volume given at any one injection site should not exceed 10 ml. The injection should only be given in the neck.

Sheep: 25 mg of florfenicol/kg bodyweight (equivalent to 1 ml of the product/15 kg bodyweight) by intramuscular injection daily for three consecutive days. The volume administered per injection site should not exceed 4 ml.

Pigs: 15 mg of florfenicol/kg bodyweight (equivalent to 1 ml of the product/25 kg bodyweight) to be administered twice 48 hours apart using a 16 gauge needle. Intramuscular injection into the neck musculature at 48 hours intervals using a 16 gauge needle. The volume administered per injection site should not exceed 3 ml.

For intramuscular route, 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. Wipe the stopper before removing each dose.

USE OF FLORFENICOL

- Use a dry sterile needle and syringe. To ensure a correct dosage bodyweight should be determined as accurately as possible. Avoid underdosing. As the vial should not be withdrawn into the syringe, the user should select the most appropriate vial size according to the target species to be treated. When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid cross contamination of the stopper. The draw-off needle should be removed after treatment.

WITHDRAWAL PERIOD

- Cattle: Meat and offal: by IV route: 30 days; by SC route: 44 days. Milk: Not authorised for use in lactating animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.
- Sheep: Meat and offal: by IV route: 37 days. Milk: Not authorised for use in lactating animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

- Pigs: Meat and offal: by IV route: 18 days.

SHELF-LIFE

- Shelf-life of the veterinary medicinal product as packaged for sale: 3 years. Shelf-life after first opening the immediate packaging: 28 days.

SPECIAL PRECAUTIONS FOR STORAGE

Store below 30ºC. Do not freeze.

PACKAGING AND LABELLING

- Pack sizes: Cardboard box containing 1 vial of 100 ml. Cardboard box containing 1 vial of 250 ml. Not all pack sizes may be marketed.

MARKETING AUTHORISATION HOLDER

- LIVISTO, S.L.
- Av. Universitat Autònoma, 29, 08290 Cardanyola del Vallès, Barcelona (Spain)

MARKETING AUTHORISATION NUMBERS

UK: VM 42717/002. E: WP/104/25/02/001

REFERENCES

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COMPANY

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TREATMENT CHOICE IN RESPIRATORY DISEASES

The most outstanding features of Florfenicol: high efficacy, prolonged effect and high distribution in lungs, allow CADOREX to be a first treatment choice in respiratory diseases.

1. High efficacy
Florfenicol has demonstrated high activity against the following bacteria:

- **Cattle and Sheep**: Mannheimia haemolytica, Pasteurella multocida, Histophilus somnus and Mycoplasma spp.
- **Pigs**: Actinobacillus pleuropneumoniae, Pastereulla multocida, Bordetella Bronchiseptica, Streptoccoccus suis and Salmonella cholerasuis.

![Most frequently isolated bacteria in respiratory infections show high susceptibility, which means low florfenicol resistance.](image)

P. multocida 99% of isolates susceptible (n=150)
M. haemolytica 99% of isolates susceptible (n=71)
A. pleuropneumoniae 99% of isolates susceptible (n=159)
P. multocida 99% of isolates susceptible (n=150)

2. Prolonged effect
After only two hours of its administration, Florfenicol exhibits a post-antibiotic effect (PAE) which is above the minimum inhibitory concentrations (MIC).

The total effect of Florfenicol could last a few more hours (1-3h) due to this PAE.

3. High lung distribution
Florfenicol is widely distributed after administration, achieving high concentrations in lungs, muscle, bile, kidney and urine.

ONE PRODUCT THREE SPECIES

**Cattle**: IM- 20 mg/kg bw in 2 doses in 48h
SC- 40 mg/kg bw single dose
Subcutaneous route at the recommended dosage maintains efficacious blood levels in cattle (i.e. above the MIC50 of the main respiratory pathogens) for 63 hours.

**Sheep**: IM- 20 mg/kg bw once daily for 3 days

**Pigs**: IM- 15 mg/kg bw in 2 doses in 48h

PLASTIC VIALS
Polypropylene vials of 100 and 250 ml. This plastic-derivate material protects its content from bumps and falls making it more resistant than glass vials.