SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Florgane 300 mg/mL Suspension for Injection for Cattle and Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substance:
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-Butanol	10 mg
Potassium metabisulfite (E 224)	0.2 mg
Carmellose sodium	
Povidone K12	
Lecithin (Soybean origin)	
Sodium citrate	
Potassium dihydrogen phosphate	
Magnesium gluconate	
Water for injection	

White to yellowish-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs.

3.2 Indications for use for each target species

Cattle:
Preventive and therapeutic treatment of respiratory tract infections in cattle caused by florfenicol susceptible *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*. The presence of the disease in the herd should be established before treatment.

Pigs:
Treatment of acute outbreaks of 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 cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not use in piglets of less than 2 kg.

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.
Official national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

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

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

People with known hypersensitivity to florfenicol or to one of the ingredients of the veterinary medicinal product should avoid contact with this veterinary medicinal product.
Avoid contact with skin and eyes. In case of dermal contact, wash the exposed area immediately with water.
Do not smoke, eat or drink while handling this veterinary medicinal product.
Take care to avoid accidental self-injection.
If such symptoms as skin rash appear after being exposed to this veterinary medicinal product, seek for medical advice. Face, lip or eye swelling, as well as difficult breathing, are serious signs requiring urgent medical assistance.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data)	Injection site swelling[1], injection site inflammation[2] Soft stool[3,4] Allergic reaction Reduced food intake[3]

[1] After intramuscular injection, usually resolves within 5 days but may persist for more than 5 days up to beyond 21 days.

2 May persist for 18 days after administration.

3 During treatment period, the treated animals recover quickly and completely upon termination of treatment.

4 Transient.

Pigs:

Very common (1 animal / 10 animals treated)	Diarrhoea[1, 2] Oedematous erythema[1,3]
Undetermined frequency (cannot be estimated from the available data)	Injection site swelling[4], injection site inflammation[5] Allergic reaction

[1] Transient.

[2] Disappear without treatment within 6 days.

[3] Peri-anal and rectal, may persist up to 1-2 weeks after treatment.

[4] Mild, after intramuscular injection, usually resolves within 6 days but may persist up to beyond 12 days.

[5] Macroscopic inflammatory lesions resolve between 12 and 20 days after administration.

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

Pregnancy and lactation:

Studies in laboratory animals have not produced any evidence of embryo- or foetotoxic potential for florfenicol.
However, the effect of florfenicol on bovine reproductive performance and pregnancy has not been assessed. Use only according to the benefit-risk assessment by the responsible veterinarian.
The safety of the veterinary medicinal product in sows during pregnancy and lactation has not been established. Use of the veterinary medicinal product during pregnancy and lactation is therefore not recommended.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Cattle:
Intramuscular use.
By one single administration in the neck musculature**:**
30 mg of florfenicol per kg body weight (eq. to 1 mL of the veterinary medicinal product per 10 kg body weight).
Do not inject more than 15 mL per injection site in cattle.

Pigs:
Intramuscular use.
By one single administration behind the ears: 22.5 mg of florfenicol per kg body weight (eq. to 0.75 mL of the veterinary medicinal product per 10 kg body weight).
Do not inject more than 5 mL per injection site in pigs.

In cattle over 150 kg and in pigs over 65 kg the total injection volume must be divided over two or more injections sites while always respecting the maximum injection

volume of 15 mL per injection site in cattle and of 5 mL per injection site in pigs. Injections may be given in alternate sides of the neck.
In case injections are given in cattle at the same side of the neck, the minimum distance between injection sites always must be 15 to 20 cm.

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

Shake before use.
Use a dry, sterile needle and syringe. Swab septum before removing each dose.
For 50 and 100 mL bottles, do not broach the vial more than 25 times. For 250 and 500 mL bottles, do not broach the vial more than 50 times.

Another type of treatment needs to be considered if response to treatment is inadequate.

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

Cattle:
None.

Pigs:
Parenteral overdoses of florfenicol in swine may cause a reduction in feeding, hydration and weight gain, and vomiting.

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: 37 days.
Not authorised for use in animals producing milk for human consumption.
Pigs:
Meat and offal: 22 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 of protein synthesis at the ribosomal level.
Florfenicol is considered to be a bacteriostatic agent, but *in vitro* studies of florfenicol demonstrate bactericidal activity against bovine strains of *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni* and porcine strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida,* the most commonly isolated bacterial pathogens involved in bovine and porcine respiratory disease.

MIC_{90} values of florfenicol against bovine and porcine respiratory pathogens

Microorganism	**MIC_{90} (µg/mL)**
Cattle	
Mannheimia haemolytica	1
Pasteurella multocida	0.5
Histophilus somni	0.5
Pigs	
Actinobacillus pleuropneumoniae	1
Pasteurella multocida	0.5

Organisms were isolated from clinical cases of bovine and porcine respiratory disease in France, Spain, UK, Germany, Ireland, Denmark, Austria, Belgium and The Netherlands during the years 2004 and 2009.
CLSI breakpoints: S ≤ 2 µg/mL, I = 4 µg/mL and R ≥ 8 µg/mL

In contrast to chloramphenicol, florfenicol does not carry the risk of inducing non-dose-related aplastic anemia in man.
Organisms resistant to chloramphenicol and thiamphenicol through the common transacetylation resistance mechanisms are less susceptible to resistance of florfenicol. However, cross-resistance to chloramphenicol and florfenicol mediated by a gene (floR) that codes for an efflux protein and is carried on plasmids has been observed in isolated cases of bovine and porcine Pasteurellae. Resistance to florfenicol and other antimicrobials has been identified in the food-borne pathogen *Salmonella typhimurium* and co-resistance to florfenicol and other antimicrobials (e.g. ceftiofur) has been identified in the microrganisms from the family *Enterobacteriaceae.*

4.3 Pharmacokinetics

Cattle:
Following the intramuscular administration of the veterinary medicinal product, florfenicol absolute bioavailability is 76% in cattle.

Following one single intramuscular administration of the veterinary medicinal product at the recommended dose of 30 mg of florfenicol per kg body weight, maximum plasma concentrations (C_{max} = 3.1 µg/mL
in young cattle and 2.5 µg/mL in calves) are attained 12 hours after administration (T_{max} = 12 h). Thereafter, there is a slow decline of florfenicol plasma levels with an average terminal half-life of about 39 h in young cattle and 47 h in calves.
Plasma concentrations above 1 µg/mL are maintained with one single intramuscular injection of 30 mg/kg body weight for on the average 45 hours in young cattle and 52 hours in calves.
Florfenicol is mainly excreted in unchanged form with urine.

Pigs:
Following one single intramuscular administration of the veterinary medicinal product at the recommended dose of 22.5 mg of florfenicol per kg body weight, mean pharmacokinetic parameters are: C_{max} = 2.2 µg/mL, T_{max} = 8 h and $T_{1/2\beta}$ = 15.5 h. Plasma concentrations above 1 µg/mL are maintained with one single intramuscular injection of 22.5 mg/kg body weight for on the average 36 hours.
Florfenicol concentrations achieved in lung tissue reflect plasma concentration, with a lung: plasma concentration ration of approximately 1, when measured in homogenised lung tissue. 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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Protect from light. Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

50 mL, 100 mL, 250 mL or 500 mL partially transparent, polypropylene, multidose bottle closed with a fluorinated bromobutyl stopper and aluminium overseal.

Carton containing either
- 1 or 12 x 50 mL,
- 1 or 12 x 100 mL,
- 1 or 12 x 250 mL,
- 1 or 12 x 500 mL,

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via the 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka bvba

7. MARKETING AUTHORISATION NUMBER

Vm 34534/3002

8. DATE OF FIRST AUTHORISATION

07 July 2010

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

August 2024

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).

Gavin Hall
Approved: 18 December 2024