

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Florkem 300 mg/ml solution for injection for cattle and pigs

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains:

**Active substance:**

Florfenicol.....300 mg

**Excipients:**

<b>Qualitative composition of excipients and other constituents</b>	<b>Quantitative composition if that information is essential for proper administration of the veterinary medicinal product</b>
Dimethylacetamide	
Diethylene glycol monoethyl ether	
Macrogol 300	

Colourless to yellow clear 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 *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 or boars intended for breeding purposes.

Do not administer in cases of hypersensitivity to the active ingredient or any of the excipients.

### 3.4 Special warnings

None

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

Wipe the stopper before removing each dose. Use a dry, sterile needle and syringe. Do not use in piglets of less than 2 kg.

Under field conditions, approximately 30% of treated pigs presented with pyrexia (40°C) associated with either moderate depression or moderate dyspnoea a week or more after administration of the second dose.

Use of 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 product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the florfenicol and may decrease the effectiveness of treatment with other antimicrobials, due to the potential for cross-resistance. Particular attention should be paid to improving farming practices to avoid any stress condition (improving management practices and by cleaning and disinfection).

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

Care should be taken when handling the product to avoid accidental self-injection. In case of accidental self-injection, seek medical advice, and show the package leaflet or the label to the physician.

People with known hypersensitivity to the components of the formulation should avoid contact with the product.

Wash hands after handling the product.

#### Special precautions for the protection of the environment:

Not applicable

### 3.6 Adverse events

#### Cattle:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Reduced food intake <sup>1</sup> Soft stool <sup>1,2</sup> Injection site reaction <sup>2,3</sup> (e.g inflammation, lesion)
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<sup>1</sup> Treated animals recover quickly and completely upon termination of treatment.

<sup>2</sup> Transient.

<sup>3</sup> May persist for up to 28 days.

Pigs:

Common (1 to 10 animals / 100 animals treated):	Anal and rectal disorder (e.g. erythema, oedema) <sup>1</sup> , Diarrhoea <sup>1,2</sup>
Very Rare (< 1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction <sup>2,3</sup> (e.g inflammation, lesion)

<sup>1</sup> May affect 50% of the animals and be observed for up to one week.

<sup>2</sup> Transient.

<sup>3</sup> Disappear within 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 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

Studies in laboratory animals have not revealed any evidence of embryo- or foeto-toxic potential for florfenicol. However, the safety of florfenicol on bovine and porcine reproductive performance and pregnancy has not been assessed. Use only according to the benefit/risk assessment by the responsible veterinarian.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

Intramuscular use. The injection should be given in the neck.

Cattle :

20 mg florfenicol per kg bodyweight, i.e. 1 ml of solution per 15 kg bodyweight, twice 48 hours apart.

Pigs :

15 mg florfenicol per kg bodyweight, i.e. 1 ml of solution per 20 kg bodyweight, twice 48 hours apart.

The dose volume given at any one injection site should not exceed 10 ml in cattle and 3 ml in pigs.

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

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.

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

In swine after intramuscular 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: 37 days

Milk: Not permitted for use in lactating 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 bacteria proteins synthesis at the ribosomal level, thus is bacteriostatic. However, in vitro tests have shown that florfenicol has a bactericidal activity against the most commonly isolated bacterial pathogens involved in respiratory diseases:

- *Histophilus somni*, *Mannheimia haemolytica* and *Pasteurella multocida* isolated from cattle
- *Actinobacillus pleuropneumonia*, and *Pasteurella multocida* isolated from pigs.

Acquired resistance to florfenicol is mediated by efflux pump resistance associated with a floR gene. Such resistance has not yet been identified in the target pathogens except for *Pasteurella multocida*. Cross resistance with chloramphenicol can occur.

Resistance to florfenicol and other antimicrobials has been identified in the food-born pathogen *Salmonella typhimurium* and co-resistance with the third-generation cephalosporins has been observed in respiratory and digestive *Escherichia coli*.

For *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* the following breakpoints have been determined for florfenicol in bovine respiratory disease; susceptible:  $\leq 2$  µg/ml, intermediate: 4 µg/ml, resistant:  $\geq 8$  µg/ml.

In bovine, 99% of *P. multocida* isolates (n=156) and 98% of *M. haemolytica* isolates (n=109) were susceptible to florfenicol (strains isolated in France in 2012).

In swine, 99% of *P. multocida* isolates (n=150) were susceptible to florfenicol (strains isolated in France in 2012).

The following Minimum Inhibitory Concentrations (MIC) have been determined for florfenicol in European isolates collected from diseased animals between 2009 to 2012:

Bacteria species	Origin	Nb of strains	CMI of florfenicol (µg/mL)	
			CMI <sub>50</sub>	CMI <sub>90</sub>
<i>Mannheimia haemolytica</i>	Cattle	147	0.7	1.0
<i>Pasteurella multocida</i>	Cattle	134	0.3	0.5
<i>Histophilus somni</i>	Cattle	64	0.2	0.2
<i>Pasteurella multocida</i>	Swine	151	0.4	0.5
<i>Actinobacillus pleuropneumoniae</i>	Swine	158	0.2	0.4

### 4.3 Pharmacokinetics

#### In cattle

Intramuscular administration of the formulation at the recommended dose of 20 mg/kg maintains efficacious blood levels for 48 hours. Maximum mean serum concentration (C<sub>max</sub>) of 3.8 µg/ml occurred 5.7 hours (T<sub>max</sub>) after dosing. The mean serum concentration 24 hours after dosing was 1.95 µg/ml. The mean elimination half life was 15.3 hours.

#### In pigs

After intramuscular administration of florfenicol, maximum serum concentration of 4.7 µg/ml is reached after 1.8 hours and the concentrations deplete with a terminal mean half-life of 14.8 hours. Serum concentrations drop below 1 µg/ml, the MIC<sub>90</sub> 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: 3years  
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 storage conditions.

### **5.4 Nature and composition of immediate packaging**

#### **Material of the primary container**

Colourless glass vial type II (20 – 50 – 100 – 250 - 500 ml).  
Translucent multi-layer plastic vials (50 – 100 – 250 – 500 ml).  
Chlorobutyl stopper type II.

#### **Pack size**

Box containing one vial of 20, 50, 100, 250 or 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 wastewater.  
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**

Ceva Animal Health Ltd

## **7. MARKETING AUTHORISATION NUMBERS**

Vm 15052/5086  
Vm 15052/3048

**8. DATE OF FIRST AUTHORISATION**

25 August 2009

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

November 2024

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT**

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

Approved 03 March 2025  
*Gavin Hall*