

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Floron 40 mg/g premix for medicated feeding stuff for pigs

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

Each gram contains:

**Active substance:**

Florfenicol 40 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>
Propylene Glycol (E1520)	10 mg
Ground Limestone	

Slightly brownish white powder.

### **3. CLINICAL INFORMATION**

#### **3.1 Target species**

Pigs (fattening pigs).

#### **3.2 Indications for use for each target species**

For the treatment and metaphylaxis of swine respiratory disease in infected herds due to *Pasteurella multocida* susceptible to florfenicol. The presence of the disease should be established in the herd before initiating metaphylactic treatment.

#### **3.3 Contraindications**

Do not use in in case of known resistance to florfenicol.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

See also section 3.7 Use during pregnancy, lactation or lay.

### 3.4 Special warnings

Animals showing a decreased appetite and/or a poor general condition should be treated by the parenteral route.

### 3.5 Special precautions for use

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

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

Use of the veterinary medicinal 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 amphenicols, due to the potential for cross-resistance.

This premix is intended for the manufacturing of solid medicated feed and cannot be used as is; the incorporation rate of the premix in feed cannot be lower than 5kg/tonne. This premix contains ground limestone, which can lead to a decrease in food consumption and to a phosphorus calcium imbalance in feed intake. Care should therefore be taken to consider the calcium content of the final medicated feeding stuff. Treatment should not exceed 5 days.

In a field clinical study, within a week after the administration of the last dose, the incidence of pigs presenting either mild depression and/or mild dyspnea and/or pyrexia (40°C) was approx. 20% in the initially severely ill animals.

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

Skin sensitisation may occur.

Avoid skin contact.

Do not handle this veterinary medicinal product in case of known sensitisation to propylene glycol.

Handle this veterinary medicinal product with care to avoid exposure during incorporation of premix into feed and administration of medicated feeding stuff to animals, taking all recommended precautions.

Wear either a disposable half-mask respirator conforming to European standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143, chemically resistant gloves, protective coveralls and goggles while incorporating the premix into feed.

Wear gloves and do not smoke, eat, or drink when handling the veterinary medicinal product or medicated feeding stuff.

Wash hands thoroughly with soap and water after use of the veterinary medicinal product or medicated feeding stuff.

Rinse thoroughly with water in case of exposure.

If you develop symptoms following exposure such as skin rash, you should seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Pigs:

Common (1 to 10 animals / 100 animals treated):	Diarrhoea*, Rectal prolapse* Perianal inflammation*
Undetermined frequency (cannot be estimated from the available data):	Hypercalcaemia

\*The effect is transient, resolves on cessation of the treatment.

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:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant and lactating sows.

Fertility:

Toxicity studies in rats have shown adverse effects on the male reproductive system. Do not use in breeding boars.

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

No data available.

### 3.9 Administration routes and dosage

In-feed use.

Dosage:

10 mg of florfenicol per kg body weight (bw) (equivalent to 250 mg the veterinary medicinal product) per day administered for 5 consecutive days.

Administration:

For a daily feed intake of 50 g/kg bodyweight, this dosage corresponds to a rate of incorporation of 5 kg of medicated premix per ton of feed, i.e. 200 ppm of florfenicol. The rate of incorporation of the medicated premix in the feed may be increased in order to achieve the required dosage on a mg/kg bodyweight basis and to take into account

the actual feed intake. Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{250 \text{ mg of the veterinary medicinal product per kg body weight and day}}{\text{Average daily feed intake (kg/animal)}} \times \text{Average pig body weight (kg)} = \text{mg the veterinary medicinal product per kg of feed}$$

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Average daily feed intake (kg/animal)

The maximum rate of incorporation is 12.5 kg/ton (500 ppm of florfenicol), higher rates of inclusion may lead to poor palatability and decreased food consumption.

Under no circumstances should the incorporation rate of the premix be below 5 kg/ton of feed.

In all cases the recommended dose of 10 mg of florfenicol per kg of body weight per day, for 5 consecutive days has to be respected.

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

The use of suitably calibrated measuring equipment is recommended.

This veterinary medicinal product should be incorporated by feed manufacturers under regulatory supervision. Calibrated mixer should be used for incorporation.

It is recommended that the veterinary medicinal product is added to the mixer containing the feeding stuff ingredients and mixed thoroughly to produce a homogeneous medicated feeding stuff. The veterinary medicinal product can be incorporated in pelleted feed preconditioned with steam at a temperature not exceeding 85 °C.

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

In the event of overdose, a reduction in food and water consumption, together with a decrease in bodyweight may be observed. There may be an increase in refused feed and an increase in serum calcium.

### **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**

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

### **3.12 Withdrawal periods**

Meat and offal: 14 days

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QJ01BA90

### 4.2 Pharmacodynamics

Florfenicol is a broad-spectrum synthetic antibiotic in the phenicol group that is active against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibition of protein synthesis at the ribosomal level and is bacteriostatic. However, bactericidal activity has been demonstrated *in-vitro* against *Pasteurella multocida* when florfenicol is present at concentrations above the MIC for 4 to 12 hours.

*In-vitro* testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory diseases in pigs, including *Pasteurella multocida*. A total of 230 *Pasteurella multocida* isolates from the respiratory tract of swine were collected between 2002 and 2006 in Belgium, Denmark, France, Germany, Italy, the Netherlands, Poland, Spain and the United Kingdom. The Minimal Inhibitory Concentration (MIC) of florfenicol against the target pathogen ranged from 0.25 to 1 µg/ml with a MIC<sub>90</sub> of 0.5 µg/ml.

The only mechanisms of chloramphenicol resistance that are known to have significant clinical relevance are CAT-mediated inactivation and efflux-pump resistance. Of these, only some of the efflux mediated resistance would also confer resistance to florfenicol and thus have the potential to be affected by florfenicol use in animals.

### 4.3 Pharmacokinetics

After administration to pigs by gavage at 10 mg/kg under experimental conditions, absorption of florfenicol was variable but peak serum concentrations of approximately 5 µg/ml were reached approximately 3 hours after dosing. The terminal half-life was between 3 and 4 hours.

When pigs were given free access, for 5 days, to feed medicated with florfenicol (premix for medicated feeding stuff) at the recommended dose of 10 mg/kg serum florfenicol concentrations exceeded 1 µg/ml for more than 16 hours each day of treatment.

Florfenicol is well absorbed when administered orally and following distribution it is rapidly eliminated in the urine and faeces in a ratio of 3:1. A fraction is excreted unchanged and the rest is metabolised into 5 major metabolites.

After parenteral dosing of florfenicol to pigs, it has been shown that lung concentrations are similar to serum concentrations.

After a single dose of 10 mg florfenicol/kg b.w. mixed with feed to fasted pigs, maximum plasma concentration of approximately 7.4 µg/ml was reached up to 1.0 hour after dosing. The terminal half-life was approximately 2.8 hours.

## **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: 4 years.

Shelf life after first opening the immediate packaging: 3 months.

Shelf life after incorporation into meal or pelleted feed: 3 months.

### **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**

PET/AL/PE foil sealed bag containing 1 kg medicated premix.

Paper/Paper/HDPE sewn bag containing 5 kg, 10 kg or 25 kg medicated premix.

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.

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**

KRKA, d.d., Novo mesto

## **7. MARKETING AUTHORISATION NUMBER**

Vm 01656/4011

## **8. DATE OF FIRST AUTHORISATION**

08 July 2010

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

February 2025

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

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).

*Gavin Hall*  
Approved: 01 May 2025