

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Floron 40 mg/g oral powder for pigs

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

Each gram contains:

#### **Active substance:**

Florfenicol 40 mg

#### **Excipients:**

| Qualitative composition of excipients and other constituents | Quantitative composition if that information is essential for proper administration of the veterinary medicinal product |
|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| 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**

In fattening pigs:

For the treatment of swine respiratory disease in individual pigs due to *Pasteurella multocida* susceptible to florfenicol.

#### **3.3 Contraindications**

Do not use in 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**

The treated pigs should be placed under special observation. On each of the five days of treatment, untreated food should not be given until the full daily amount of medicated feed has been ingested by the pigs.

If there is no significant improvement after 3 treatment days, the diagnosis should be reviewed and if necessary the treatment should be changed.

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 target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen. 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 amphenicols due to the potential for cross-resistance.

This veterinary medicinal product contains ground limestone, which can lead to a decrease in food consumption and to a phosphorus calcium imbalance in feed intake. Therefore the calcium content of the final food shall be considered.

Treatment should not exceed 5 days.

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

Skin sensitisation may occur.

Avoid skin contact.

People with known hypersensitivity to propylene glycol should avoid contact with the veterinary medicinal product.

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

Personal protective equipment consisting of either a disposable half-mask respirator conforming to European standard EN 149 or a non-disposable respirator conforming to European Standard EN 140 with a filter conforming to EN 143, chemically resistant gloves, protective coveralls and goggles should be worn when handling the veterinary medicinal product while incorporating the powder into feed.

Wear gloves when handling the veterinary medicinal product or feed containing the product and do not smoke, eat, or drink. Wash hands thoroughly with soap and water after use of the veterinary medicinal product or medicated feed.

In case of accidental exposure, wash the affected area thoroughly with clean running water.

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

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

Not applicable.

### 3.6 Adverse reactions (frequency and seriousness)

Pigs:

|                                                                          |                                                        |
|--------------------------------------------------------------------------|--------------------------------------------------------|
| Common<br>(1 to 10 animals / 100 animals treated):                       | Diarrhoea*, Rectal prolapse*<br>Perianal inflammation* |
| Undetermined frequency<br>(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 contact details.

### 3.7 Use during pregnancy, lactation or lay

#### Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in sows during pregnancy and lactation. The use is not recommended during pregnancy and lactation.

#### 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

For use in individual pigs.

In feed use. The veterinary medicinal product is recommended for use with non-pelleted feed.

#### Dosage:

10 mg of florfenicol per kg body weight (bw) (equivalent to 250 mg the veterinary medicinal product) per day mixed in a portion of the daily feed ration on 5 consecutive days.

#### Administration:

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

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

$$\begin{array}{ccc} 250 \text{ mg of the} & & \\ \text{veterinary medicinal} & \times & \text{body weight of the pig} \\ \text{product per kg body} & & \text{(kg)} \\ \text{weight and day} & & \end{array}$$

Special care has to be taken that the total dose is ingested.

The powder should be mixed into some of the feed to ensure it is thoroughly distributed. This mixture must be administered before the actual feed. The maximum concentration is 500 mg florfenicol/kg feed, higher concentrations may lead to poor palatability and decreased food consumption.

In cases of severe disease or inappetence the animals should be treated by the parenteral route.

For treatment of groups of pigs, use an appropriate premix incorporated into medicated feedingstuff by an authorised feed manufacturer.

### **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**

Not applicable.

### **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 152 *Pasteurella multocida* isolates from the respiratory tract of swine were collected between 2009 and 2012 in Belgium, Denmark, France, Germany, 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 of 10 mg/kg b.w. to pigs under experimental conditions, mean maximal serum concentrations of approximately 7.4 µg/ml were reached within 1.5 hours after dosing. The terminal half-life was between approximately 2 and 4 hours. After a single treatment the serum concentrations of florfenicol remained above 1 µg/ml for 6 to 12 hours.

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.

### **5. PHARMACEUTICAL PARTICULARS**

#### **5.1 Major incompatibilities**

None known.

#### **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

#### **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 250 g, 1 kg or 3 kg of oral powder.  
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**

KRKA, d.d., Novo mesto

### **7. MARKETING AUTHORISATION NUMBERS**

Vm 01656/3084

Vm 01656/5084

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

10 April 2013

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

May 2026

### **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 10 June 2026

*Gavin Hall*