SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floron 40 mg/g oral powder for swine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Florfenicol 40 mg

Excipients:
Propylene Glycol (E1520) 10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral powder.
Slightly brownish white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pig (fattening pigs).

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) Special precautions for use in animals

The product should be used in conjunction with susceptibility testing and take into account official and local policy relating to the use of antimicrobials.
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 amphenicols due to the potential for cross-resistance.
This 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.

ii) 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 product in case of known sensitisation to propylene glycol.
Handle this product with care to avoid exposure during incorporation of the powder into feed and administration of feed 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 powder into feed.
Wear gloves and do not smoke, eat, or drink when handling the product or medicated feed.
Wash hands thoroughly with soap and water after use of the product or medicated feed.
Rinse thoroughly with water in case of exposure.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and take the package leaflet or the label with you.

4.6 Adverse reactions (frequency and seriousness)

Commonly observed adverse effects are diarrhoea perianal inflammation and rectal eversion. These effects are transient, resolving on cessation of treatment. Increased serum calcium may also be observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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

therefore not recommended.
Do not use in breeding boars because toxicity studies in rats have shown adverse effects on the male reproductive system: See section 4.3 contraindications.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

For use in individual pigs.

For use in feed. The 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:
In order to ensure correct dosing and to prevent underdosing, the body weight shall be calculated as precisely as possible. The necessary amount of the product shall be weighed on a calibrated scale.

The correct dosage can be calculated as follows:

250 mg of the veterinary medicinal product per kg body weight and day	X	body weight of the pig (kg)

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal: 14 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use, Amphenicols
ATC vet code: QJ01BA90

5.1 Pharmacodynamic properties

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 1µg/ml with a MIC_{90} of 0.5µg/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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol (E1520)
Ground Limestone

6.2 Major incompatibilities

None known.

6.3 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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

8. MARKETING AUTHORISATION NUMBER

Vm 01656/4053

9. DATE OF FIRST AUTHORISATION

10 April 2013

10. DATE OF REVISION OF THE TEXT

February 2018

Approved 20 February 2018