

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BAG}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floron 40 mg/g premix for medicated feeding stuff

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains 40 mg of florfenicol.

3. PACKAGE SIZE

1 kg
5 kg
10 kg
25 kg

4. TARGET SPECIES

Pigs (fattening pigs)



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In-feed use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 14 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Shelf life after incorporation into meal or pelleted feed: 3 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/4011

15. BATCH NUMBER

Lot {number}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each gram contains:

Active substance:

Florfenicol 40 mg

Excipients:

Propylene Glycol (E1520) 10 mg

Slightly brownish white powder.

3. Target species

Pigs (fattening pigs).



4. Indications for use

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.

5. 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 6. Special warnings.

6. Special warnings

Special warnings:

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

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.

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.

Overdose:

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.

Special restrictions for use and special conditions for use:

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

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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:

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

Average daily feed intake (kg/animal)

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.

9. Advice on correct administration

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.

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.

10. Withdrawal periods

Meat and offal: 14 days

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

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

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

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01656/4011

Bag containing 1 kg, 5 kg, 10 kg or 25 kg.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
E-mail: info.uk@krka.biz

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V Veterinary medicinal product subject to prescription

Gavin Hall
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