PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PET/AL/PE foil sealed bag containing 1 kg medicated premix.
Paper/Paper/HDPE sewed bag containing 5 kg, 10 kg or 25 kg medicated premix.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floron 40 mg/g Premix for Medicated Feeding Stuff for Swine
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each g of slightly brownish white powder contains 40 mg of florfenicol with 10 mg of propylene glycol (E1520).

3. PHARMACEUTICAL FORM

Premix for Medicated Feeding Stuff

4. PACKAGE SIZE

1 kg
5 kg
10 kg
25 kg

5. TARGET SPECIES

Pigs (Fattening pigs)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
In-feed use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 14 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the user warnings in the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf-life after first opening the immediate packaging: 3 months
Shelf life after incorporation into meal or pelleted feed: 3 months

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 01656/4011

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:

Floron 40 mg/g Premix for Medicated Feeding Stuff for Swine

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floron 40 mg/g Premix for Medicated Feeding Stuff for Swine
Florfenicol

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each g of slightly brownish white powder contains 40 mg of florfenicol with 10 mg of propylene glycol (E1520).

4. INDICATION(S)

In fattening pigs:
For the treatment and prevention 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 preventive treatment.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, or to any of excipients.
Do not use in case of known resistance to florfenicol.
See also section 12. Special warning(s).

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (Fattening pigs)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

To be administered orally, in medicated feeding stuff.

Dosage: 10 mg of florfenicol per kg body weight (bw) (equivalent to 250 mg of 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 Premix for Medicated Feeding Stuff per ton of feed, i.e. 200 ppm of florfenicol.
The rate of incorporation of the Premix for Medicated Feeding Stuff 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. Thus, the inclusion level may need adjusting as follows to give the correct dose.

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

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 to avoid underdosing. The required doses should be measured by suitably calibrated weighing equipment.

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 for Medicated Feeding Stuff be below 5 kg/ton of feed.

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

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

10. WITHDRAWAL PERIOD

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.
Shelf-life after first opening the immediate packaging: 3 months
Shelf life after incorporation into meal or pelleted feed: 3 months

12. SPECIAL WARNING(S)

Special warnings for each target species:
Animals showing a decreased appetite and/or a poor general condition should be treated by the parenteral route.

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 other amfenicols, due to the potential for crossresistance.
This premix is intended for the manufacturing of solid medicated feeding stuff and cannot be used as is; the incorporation rate of the premix in feed cannot be lower than 5 kg/ton.
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 product in case of known sensitisation to propylene glycol.

Handle this product with care to avoid exposure during incorporation of premix 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 premix into feed.
Wear gloves and do not smoke, eat, or drink when handling the product or medicated feeding stuff.
Wash hands thoroughly with soap and water after use of the 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 in sows during pregnancy and lactation.
Toxicity studies in rats have shown adverse effects on the male reproductive system.
Do not use in pregnant and lactating sows.
Do not use in breeding boars.

Overdose (symptoms, emergency procedures, 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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

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

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Approved: 26 October 2017