ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PET/AL/PE foil sealed bag containing 250 g, 1 kg or 3 kg of oral powder.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floron 40 mg/g oral powder for swine
Florfenicol

2. STATEMENT OF ACTIVE SUBSTANCES

Each g of slightly brownish white powder contains 40 mg of florfenicol.

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

250 g
1 kg
3 kg

5. TARGET SPECIES

Pig (fattening pigs)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Top-dressing use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
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 container: 3 months
Once broached/opened, use by…

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(S)

Vm 01656/4053

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Floron 40 mg/g oral powder 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 oral powder 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 of swine respiratory disease in individual pigs due to *Pasteurella multocida* susceptible to florfenicol.

5. 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.
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.

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).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.(Poland)

7. TARGET SPECIES

Pig (fattening pigs)

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

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 of 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

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 container: 3 months

12. SPECIAL WARNING(S)

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.

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.

Pregnancy, lactation and fertility:
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 5. contraindications.

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.

User warnings
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 product 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.

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 products 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 250 g, 1 kg or 3 kg of oral powder.
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.

Approved 20 February 2018