SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORTEK 40 mg/g Premix for medicated feeding stuff for pigs [ES, CY, HU, PT]
K-FLOR 40 mg/g Premix for medicated feeding stuff for pigs [IT]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g 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

Premix for medicated feeding stuff.
White to off-white, free flowing powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (fattening pigs)

4.2 Indications for use, specifying the target species

For the treatment and metaphylaxis of swine respiratory disease caused by *Pasteurella multocida* susceptible to florfenicol in infected herds. The presence of the disease in the herd must be established before the product is used.

4.3 Contraindications

Do not administer to boars intended for breeding.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

Good clinical practice requires that treatment should be based on sensitivity tests of bacteria isolated from diseased animals. If this is not possible, treatment should be based on local (regional, farm level) epidemiological information on the sensitivity of different strains of bacterial species usually involved in the infectious process.
This premix is intended for the manufacturing of solid medicated feed and cannot be used as it is; the incorporation rate of the premix in feed cannot be lower than 5kg/ton.

This premix contains calcium carbonate, 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 feed.
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 dyspnoea 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 or eyes contact with the veterinary medicinal product.
Do not handle this product in case of known sensitization to florfenicol or 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.
Wash hands thoroughly with soap and water after use of the product or medicated feed
In case of skin contact, wash immediately the affected area and remove contaminated clothing. In case of contact with the eyes, wash immediately with plenty of water.
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.
Do not smoke, eat, or drink when handling veterinary medicinal product or medicated feed.

Other precautions

Florfenicol is toxic for cyanobacteria and groundwater organisms.

4.6 Adverse reactions (frequency and seriousness)

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

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 during pregnancy and lactation. Therefore the use is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

In-feed use
Dosage:
10 mg of florfenicol per kg bodyweight (equivalent to 250 mg of 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 per ton of feed.
Thus, the inclusion level may need adjusting as follows to give the correct dose.

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

The maximum rate of incorporation is 12.5 kg/ton, 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.

It is not necessary to carry out a dilution prior to incorporation into the 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 bodyweight should be determined as accurately as possible to avoid underdosing. The required doses should be measured by suitably calibrated weighing equipment.

A horizontal ribbon mixer should be used to incorporate the veterinary medicinal product into the feeding stuff. 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. Medicated feed may also then be pelleted. Pelleting conditions include a pre-conditioning step with steam and then the mixture is passed through a pelleter or extruder under normal conditions.

During granulation, it is advisable to maintain a temperature below 85ºC.

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)

Pigs (fattening pigs)
Meat and offal: 14 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use. Amphenicols.
ATCvet code: QJ01BA90.

5.1 Pharmacodynamic properties

Florfenicol is a broad-spectrum synthetic antibiotic in the phenicol group. 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 *Pasteurella multocida*.
Florfenicol resistance is mainly due to the presence of specific efflux pumps (*e.g.* florR) or multi-substrate (*e.g.* AcrAB-TolC). The genes corresponding to these mechanisms are encoded in genetic elements such as plasmids, transposons or gene cassettes. Cross resistance with chloramphenicol is possible.

5.2 Pharmacokinetic particulars

After administration to pigs by gavage at 10 mg/kg under experimental conditions, absorption of florfenicol was variable but peak serum concentrations of approximately 5 µg/ml were reached approximately 3 hours after dosing. The terminal half-life was between 3 and 4 hours. When pigs were given free access, for 5 days, to feed medicated with the veterinary medicinal product at the recommended dose of 10 mg/kg serum florfenicol concentrations exceeds 1 µg/ml for more than 16 hours each day of treatment.

Florfenicol is well absorbed when administered orally and following distribution it is rapidly excreted in the urine and faeces in a ration 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.

5.3 Environmental properties

Florfenicol is toxic for cyanobacteria and groundwater organisms.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol (E 1520)
Calcium Carbonate

6.2 Major Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 3 months
Shelf life after incorporation into meal or pelleted feed: 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

Kraft paper bag of three ply with an inner layer of LDPE.

Pack sizes:

25 Kg bag

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 product should be disposed of in accordance with local requirements.
Dangerous for aquatic organisms such as cyanobacteria. Do not contaminate surface waters with the product or with used containers.

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS KARIZOO, S.A.
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Spain

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.