SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenflor 300 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Florfenicol……300 mg

Excipients:
Propylene glycol…..150 mg
Macrogol 400……481,25 mg
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
A light yellow to yellow, clear, viscous liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Treatment of acute outbreaks of respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

4.3 Contraindications

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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Wipe the stopper before removing each dose. Use a dry, sterile syringe and needle.

Do not use in piglets of less than 2 kg.

The product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.

Use a suitable draw-off needle or automatic dosing syringe to avoid excessive puncturing of the closure.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to florfenicol, propylene glycol and polyethylene glycols should avoid contact with the veterinary medicinal product.
In case of accidental contact with eyes, rinse immediately with plenty of water.

Special precautions for the protection of the environment

Not applicable.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Pigs:

Very common (>1 / 10 animals treated):	Diarrhoea[1] Peri-anal and rectal erythema/oedema[1] Pyrexia (40 °C) associated with either moderate depression or moderate dyspnea[2]
Undetermined frequency (cannot be estimated from the available data):	Injection site swelling[3] Injection site inflammation[4]

May affect up to 50% of the animals; can be observed for one week.

Approximately 30% of treated pigs presented with week or more after administration of the second dose.

May last up to 5 days.
May last up to 28 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not revealed any evidence of embryo- or foeto-toxic potential for florfenicol. However, the safety of the product in sows has not been established during pregnancy and lactation.

The use is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

Intramuscular use.

15 mg/kg bodyweight (1 ml per 20 kg) by intramuscular injection into the neck muscle twice at 48 hour intervals using a dry, sterile 16-gauge needle.

The volume administered per injection site should not exceed 3 ml.
It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours after the second injection.

If clinical signs of respiratory disease persist 48 hours after the last injection, treatment should be changed using another formulation or another antibiotic and continued until clinical signs have resolved.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

In swine after administration of 3 times the recommended dose or more a reduction in feeding, hydration and weight gain has been observed.

After administration of 5 times the recommended dose or more vomiting has also been noted.

4.11 Withdrawal period

Meat and offal: 18 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use

ATCVet code: QJ01BA90

5.1 Pharmacodynamic properties

Florfenicol is a broad-spectrum synthetic antibiotic 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 *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

In-vitro testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory diseases in pigs, including *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

Acquired resistance to florfenicol is mediated by efflux pump resistance associated with a *floR* gene. In target pathogens, such resistance has only been identified in *Pasteurella multocida*. Cross resistance with chloramphenicol can occur.

5.2 Pharmacokinetic particulars

After a single intramuscular administration of the recommended dose of 15 mg/kg maximum plasma concentrations of 2.08 µg/ml were reached after 2 hours.

The harmonic mean elimination half life was 10.37 hours.
After administration to pigs by the intramuscular route, florfenicol is rapidly excreted, primarily in urine. The florfenicol is extensively metabolised.

Serum concentrations persist above 1 µg/ml for 12 to 24 hours following IM administration. Florfenicol concentrations achieved in lung tissue reflect plasma concentrations, with a lung: plasma concentration ratio of approximately 1.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethyl sulfoxide
Propylene glycol
Macrogol 400

6.2 Major Incompatibilities

In the absence of incompatibility studies, this veterinary medicinal product should 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: 28 days.

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

50, 100 and 250 ml Type I amber glass bottle closed with a bromobutyl rubber stopper and aluminium seal.

1 bottle (50 ml) in cardboard box.
1 bottle (100 ml) in cardboard box.
1 bottle (250 ml) in cardboard box.

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

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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 01656/5065

9. DATE OF FIRST AUTHORISATION

04 July 2007

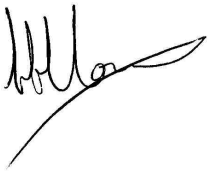
10. DATE OF REVISION OF THE TEXT

November 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the “Product Information Database” or “PID” on www.gov.uk



Approved 10 November 2023