SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenflor 300 mg/ml solution for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Florfenicol 300 mg

Excipients:

Qualitative composition of excipients and other constituents
Dimethyl sulfoxide
Propylene glycol
Macrogol 400

A light yellow to yellow, clear, viscous liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

Diseases caused by florfenicol susceptible bacteria.
Treatment and metaphylaxis of respiratory tract infections in cattle due to *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*, where the presence of the disease in the herd has been established.

3.3 Contraindications

Do not use in adult bulls intended for breeding purposes.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in case of resistance to the active substance.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Swab septum before removing each dose. Use a dry, sterile syringe and needle.
The veterinary medicinal product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol and may decrease the effectiveness of treatment with other amfenicols, due to the potential for cross resistance.

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.
Do not use the veterinary medicinal product in known cases of sensitivity to propylene glycol.

Special precautions for the protection of the environment:

The use of this veterinary medicinal product may pose a risk for terrestrial plants, cyanobacteria and groundwater organisms.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic reaction
Undetermined frequency (cannot be estimated from the available data)	Reduced food intake[1] Loose stool[1] Injection site swelling[2] Injection site inflammation[3]

[1]Quick and complete recovery upon termination of treatment.
[2]After intramuscular administration: may persist for 14 days; after subcutaneous administration: may persist for 41 days.
[3]After intramuscular administration: may persist for 32 days; after subcutaneous administration: may persist for 41 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 its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Studies in laboratory animals have not revealed any evidence of embryo- or foetotoxic potential for florfenicol.
However, the effect of florfenicol on bovine reproductive performance and pregnancy has not been assessed. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Fertility:

Do not use in adult bulls intended for breeding purposes.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular and subcutaneous use.

For treatment:
Intramuscular use: 20 mg/kg bodyweight (1 ml/15 kg) to be administered twice 48 hours apart.

Subcutaneous use: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only using a 16 gauge needle.

For metaphylaxis where the presence of the disease in the herd has been established:
Subcutaneous use: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only using a 16 gauge needle.

The dose volume given at any one injection site should not exceed 10 ml.
The injection should only be given in the neck.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal:	by i.m. (at 20 mg/kg bodyweight, twice):	30 days
	by s.c (at 40 mg/kg bodyweight, once):	44 days

Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01BA90

4.2 Pharmacodynamics

Florfenicol is a synthetic broad spectrum antibiotic effective against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at the ribosomal level and is bacteriostatic. Laboratory tests have shown that florfenicol is active against the most commonly isolated bacterial pathogens involved in bovine respiratory disease which include *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*.
Florfenicol is considered to be a bacteriostatic agent, but *in vitro* studies of florfenicol demonstrated bactericidal activity against *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*.

Acquired resistance to florfenicol is mediated by efflux pump resistance associated with a *floR* gene. Such resistance has been identified in the target pathogens *Pasteurella multocida* and *Mannhemia haemolytica*. Cross resistance with chloramphenicol can occur. Resistance to florfenicol and other antimicrobials has been identified in the food-borne pathogen *Salmonella typhimurium.* Co-resistance with the third-generation cephalosporins has been observed in respiratory and digestive *Escherichia coli*.

4.3 Pharmacokinetics

Intramuscular administration at the recommended dose of 20 mg/kg maintains efficacious blood levels in cattle for 48 hours. Maximum mean plasma concentration (C_{max}) of 3.86 µg/ml occurs at 5 hours (T_{max}), after dosing. The mean plasma concentration 24 hours after dosing was 1.56 µg/ml.

The harmonic mean elimination half life was 18.8 hours.

After subcutaneous administration of the recommended dose of 40 mg florfenicol/kg b.w., maximum plasma concentration (C_{max}) of approximately 3.5 µg/ml occurs approximately 7.0 hours (T_{max}) after dosing. The mean plasma concentration 24 hours after dosing is approximately 2 µg/ml.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I amber glass bottle closed with a bromobutyl rubber stopper and aluminium seal.
Pack sizes:
Cardboard box containing one bottle of 50 ml.
Cardboard box containing one bottle of 100 ml.
Cardboard box containing one bottle of 250 ml.

Not all pack sizes may be marketed.

5.5 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.

The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for fish and other aquatic organisms.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

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

7. MARKETING AUTHORISATION NUMBERS

GB Vm 01656/5116
NI Vm 01656/3116

8. DATE OF FIRST AUTHORISATION

04 July 2007

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 11 December 2024