PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenflor 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 300 mg of florfenicol

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

i.m., s.c.
The injection should only be given in the neck.

7. WITHDRAWAL PERIODS

Withdrawal period:

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.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within: 28 days.
Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

GB Vm 01656/5116
NI Vm 01656/3116

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenflor 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE

Each ml contains 300 mg of florfenicol.

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
i.m., s.c.
The injection should only be given in the neck.

5. WITHDRAWAL PERIODS

Withdrawal period:

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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.
Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fenflor 300 mg/ml solution for injection for cattle

2. Composition

Each ml contains:

Active substance: Florfenicol 300 mg

A light yellow to yellow, clear, viscous liquid.

3. Target species

Cattle.

4. Indications for use

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.

5. 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.

6. Special warnings

Special precautions for use in animals
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.

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.

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

7. 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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the local

representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system https://www.gov.uk/report-veterinary-medicine-problem.

8. Dosage for each species, routes and method of administration

Intramuscular and subcutaneous use.

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

9. Advice on correct administration

The injection should only be given in the neck.
Swab septum before removing each dose. Use a dry sterile 16 gauge needle and syringe.
The dose volume given at any one injection site should not exceed 10 ml.
To ensure a correct dosage, body weight should be determined as accurately as possible.

10. 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.

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 immediate packaging: 28 days.

12. Special precautions for the disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

GB Vm 01656/5116
NI Vm 01656/3116

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

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

Local representative and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
info.uk@krka.biz

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

17. Other information

POM-V Veterinary medicinal product subject to prescription