PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenflor 300 mg/ml solution for injection for cattle
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:
Florfenicol……300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For intramuscular and subcutaneous use.
The injection should only be given in the neck.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days
by SC (at 40 mg/kg bodyweight, once): 44 days

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

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:
Care should be taken to avoid accidental self-injection.

10. EXPIRY DATE

EXP:
Shelf life after first opening the immediate container: 28 days.
Once 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

Vm 01656/4026

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenflor 300 mg/ml solution for injection for cattle
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:
Florfenicol……300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For intramuscular and subcutaneous use.
The injection should only be given in the neck.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days
by SC (at 40 mg/kg bodyweight, once): 44 days

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

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:
Care should be taken to avoid accidental self-injection.

10. EXPIRY DATE

EXP:
Shelf life after first opening the immediate container: 28 days.
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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 REACH AND SIGHT 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

Vm 01656/4026

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:
Fenflor 300 mg/ml solution for injection for cattle

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

Fenflor 300 mg/ml solution for injection for cattle
Florfenicol

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml of a light yellow to yellow, clear liquid contains:

Florfenicol……300 mg

4. INDICATION(S)

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 case of hypersensitivity to the active substance or to any of the excipients.
Do not use in case of resistance to the active substance.

6. ADVERSE REACTIONS

A decrease in food consumption and transient softening of the faeces may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.

Administration of the product by the intramuscular route may cause swelling at the injection site which may persist for 14 days. Inflammation at the injection site may persist up to 32 days after administration.

Administration of the product by the subcutaneous route may cause swelling and inflammation at the injection site which may persist at least for 41 days.

On very rare occasions, anaphylactic reactions have been reported.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

For treatment:
IM route: 20 mg/kg bodyweight (1 ml/15 kg) to be administered twice 48 hours apart.
SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only.
Intramuscular and subcutaneous injection.

For metaphylaxis where the presence of the disease in the herd has been established:
SC route: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only.
Subcutaneous injection.

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 to avoid under dosing.

10. WITHDRAWAL PERIOD

Meat and offal:	by IM (at 20 mg/kg bodyweight, twice):	30 days
	by SC (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.

Shelf-life after first opening the immediate container: 28 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after {EXP}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

For animal treatment only.
Do not exceed the recommended dose.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Only administer by the routes outlined under point 8 and 9.
The product should be used in conjunction with susceptibility testing. Official and local antimicrobial policies should be taken into account.
Use of the 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.

The effect of florfenicol on bovine reproductive performance and pregnancy has not been assessed so it should only be used according to the benefit/risk assessment by your vet.
This veterinary medicinal product should not be mixed with other veterinary medicinal products.

User warnings:
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 product in known cases of sensitivity to propylene glycol.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
50 ml
100 ml
250 ml

Not all pack sizes may be marketed.

KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
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