PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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:

Active substance:
Florfenicol……300 mg

Excipients:
Propylene glycol…..150 mg
Macrogol 400……481,25 mg

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Pigs

5. INDICATION(S)

6. ROUTE(S) OF ADMINISTRATION

Intramuscular use

7. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 18 days

8. EXPIRY DATE

Exp.
Once broached, use within 28 days.

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

14. MARKETING AUTHORISATION NUMBER

Vm 01656/5065

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (Veterinary medicinal product subject to prescription'.)

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 AND OTHER SUBSTANCES

Each ml contains:

Active substance: Florfenicol……300 mg

Excipients:
Propylene glycol…..150 mg
Macrogol 400…….481,25 mg

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Intramuscular use

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 18 days

6. EXPIRY DATE

Exp.
Once broached, use within 28 days

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

9. BATCH NUMBER

Lot

10. SPECIAL WARNING(S), IF NECESSARY

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

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

POM-V (Veterinary medicinal product subject to prescription'.)

50 ml
100 ml
250 ml

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenflor 300 mg/ml solution for injection for pigs

2. COMPOSITION

Each ml contains:

Active substance:
Florfenicol……300 mg

Excipients:
Propylene glycol…..150 mg
Macrogol 400……481,25 mg

A light yellow to yellow, clear, viscous liquid.

3. TARGET SPECIES

Pigs.

4. INDICATION(S) FOR USE

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

5. 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.

6. SPECIAL WARNING(S)

Special precautions for safe use in the target species:
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.

Pregnancy and lactation:
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.

Interactions with other medicinal products and other forms of interaction:
No data available.

Overdose:
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.

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

7. ADVERSE REACTIONS

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]

[1] May affect up to 50% of the animals; can be observed for one week.
[2]Approximately 30% of treated pigs presented with week or more after administration of the second dose.
[3]May last up to 5 days.
[4]May last up to 28 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 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.}.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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

Intramuscular use.

15 mg/kg bodyweight (1 ml per 20 kg) by intramuscular injection into the neck muscle twice at 48 hours interval.

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.

9. ADVICE ON CORRECT ADMINISTRATION

The injection should only be given in the neck.
Wipe the stopper before removing each dose. Use a dry, sterile 16-gauge needle.
Not more than 3 ml should be administered at one injection site.
To ensure a correct dosage, body weight should be determined as accurately as possible.

10. WITHDRAWAL PERIOD

Meat and offal: 18 days

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 container: 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label and carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL

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. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

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.

Vm 01656/5065

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

November 2023

Find more product information by searching for the Product Information Database 'PID' 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

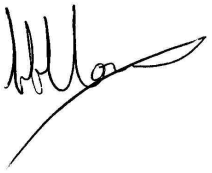
Local representative and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
info.uk@krka.biz

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

17. OTHER INFORMATION

POM-V (‘To be supplied only on veterinary prescription’)

For animal treatment only.



Approved 10 November 2023