PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor 100 mg/ml solution for injection for cattle and pigs (sows)
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of solution for injection contains 100 mg of marbofloxacin.

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 for administration instructions, user warnings and other directions.
Cattle:IV,SC, IM
Pigs (sows): IM

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
Meat and offal: 6 days
Milk: 36 hours

Pigs (sows):
Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Once broacheduse by…
Shelf-life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.
Do not freeze.

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 REACH AND SIGHT 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 01656/4059

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor 100 mg/ml solution for injection for cattle and pigs (sows)
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of solution for injection contains 100 mg of marbofloxacin.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet for administration instructions, user warnings and other directions.

Cattle:IV,SC, IM
Pigs (sows): IM

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
Meat and offal: 6 days
Milk: 36 hours

Pigs (sows):
Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Once broached, use by…
Shelf-life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.
Do not freeze.

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 01656/4059

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor 100 mg/ml solution for injection for cattle and pigs (sows)
Marbofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

100 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle:IV,SC, IM
Pigs (sows): IM

5. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
Meat and offal: 6 days
Milk: 36 hours

Pigs (sows):
Meat and offal: 4 days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP
Once broached, use by…
Shelf-life after first opening the immediate packaging: 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET
Quiflor 100 mg/ml solution for injection for cattle and pigs (sows)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor 100 mg/ml solution for injection for cattle and pigs (sows)
Marbofloxacin

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

Each ml of solution for injection contains:

Active substance:
Marbofloxacin 100 mg

Excipients:
Disodium edetate 0.10 mg
Monothioglycerol 1 mg
Metacresol 2 mg

Clear, greenish yellow to brownish yellow solution.

4. INDICATION(S)

Cattle
Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma bovis*.
Treatment of acute mastitis caused by *Escherichia coli* strains sensitive to marbofloxacin during the lactation period.

Sows
Treatment of Metritis Mastitis Agalactia Syndrome caused by bacterial strains sensitive to marbofloxacin.

The product should only be used based on susceptibility testing.

5. CONTRAINDICATIONS

Do not administer in animals with known hypersensitivity to marbofloxacin or any other quinolone or to any of the excipients.
Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

6. ADVERSE REACTIONS

Administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which persist at least 12 days after injection. However, in cattle, subcutaneous route was shown to be better tolerated locally than intramuscular route. Therefore, the subcutaneous route is recommended in heavy cattle.

For the injections, the neck should be preferred in cattle and pigs.
No other undesirable effects have been observed in cattle and pigs.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pigs (sows).

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

The recommended dosage is 2mg/kg/day (1ml/50kg) in a single daily injection by intramuscular, subcutaneous or intravenous routes in cattle and by intramuscular route in pigs.

Treatment durations are 3 days in pigs and 3 to 5 days in cattle.

To ensure administration of a correct dose, body weight should be determined as accurately as possible, to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

In order to reduce the risk of particulate contamination of the product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.

10. WITHDRAWAL PERIODS

Cattle:
Meat and offal: 6 days
Milk: 36 hours

Pigs (sows):
Meat and offal: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original package in order to protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Official and local antimicrobial policies should be taken into account when the product is used. Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials. Whenever possible, fluoroquinolones should only be used based on susceptibility testing. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Studies in laboratory animals (rats, rabbits) did not show any teratogenic, embryotoxic effects or any maternal toxicity of marbofloxacin.
Safety of the product has been shown in cows during gestation and in suckling pigs and calves when used in cows and sows.
May be used in pregnant and lactating cows and sows.
In the case of use in the cow during lactation, see paragraph 10. Withdrawal Periods.

No sign of overdose has been observed after administration of 3 times the recommended dose.
Overdose may cause acute signs in the form of neurological disorders which should be treated symptomatically.

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

User Warnings
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
Avoid contact of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water.
Avoid accidental self-injection, since this can cause local irritation. In case of self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Solution for injection is available in glass bottles of 50 ml, 100 ml and 250 ml solution for injection in a box.

Not all pack sizes may be marketed.

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

KRKA UK Ltd
United Kingdom
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pharmacovigilance.uk@krka.biz

Approved: 26 October 2017