PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 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 before use.
Cattle: IV, SC, IM
Pigs (sows): IM

8. WITHDRAWAL PERIOD

Cattle:
8 mg/kg single dose
Meat and offal: 3 days
Milk : 72 hours

2 mg/kg single daily injection, for 3 to 5 days:
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

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(S)

Vm: 01656/4055
POM-V Prescription Only Medicine-Veterinarian

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 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 before use.
Cattle: IV, SC, IM
Pigs (sows): IM

8. WITHDRAWAL PERIOD

Cattle:
8 mg/kg single dose
Meat and offal: 3 days
Milk : 72 hours

2 mg/kg single daily injection, for 3 to 5 days:
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(S)

Vm: 01656/4055
POM-V Prescription Only Medicine-Veterinarian

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor Multi 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

Cattle:
8 mg/kg single dose
Meat and offal: 3 days
Milk : 72 hours

2 mg/kg single daily injection, for 3 to 5 days:
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 Multi 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 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

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

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

1 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, Mycoplasma bovis* and *Histophilus somni*.
Treatment of acute mastitis caused by *Escherichia coli* strains sensitive to marbofloxacin during the lactation period.

Sows
Treatment of Metritis Mastitis Agalactia Syndrome (postpartum dysgalactiae syndrome, PDS) caused by bacterial strains sensitive to marbofloxacin.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active substance 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.

No other undesirable effects have been observed in 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

Cattle:
Respiratory infections:

This product may be administered as a single dose given on one day only or as a multiple dose injection given over 3 – 5 days.

Single dose - Intramuscular use:
The recommended dosage is 8 mg/kg bodyweight i.e. 2 ml/25 kg bodyweight in a single injection with the exception of the situations listed below.
If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.

Multiple dose - Intramuscular, intravenous or subcutaneous use:
The recommended dosage is 2mg/kg bodyweight i.e. 1 ml/50 kg in a single daily injection for 3-5 days. This dosing regimen should be used for treatment of specific cases (such as those which require intravenous treatment, for instance in case of *Mycoplasma*).

Acute mastitis:
- *Intramuscular, intravenous or subcutaneous use:*
The recommended dosage is 2 mg/kg i.e. 1 ml/50 kg bodyweight in a single daily injection, for 3-5 days.

Pigs (sows):
- *Intramuscular use:*
The recommended dosage is 2 mg/kg i.e.1 ml/50kg bodyweight in a single daily injection, for 3 days.

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 both cattle and pigs, injections should preferably be given in the neck.
The cap may be safely punctured up to 25 times. The user should choose the most appropriate vial size according to the target species to treat.

10. WITHDRAWAL PERIODS

Cattle:
8 mg/kg single dose
Meat and offal: 3 days
Milk : 72 hours

2 mg/kg single daily injection, for 3-5 days:
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.

12. SPECIAL WARNING(S)

Official and local antimicrobial policies should be taken into account when the product is used. Fluoroquinoles 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.
The efficacy data showed that the product has insufficient efficacy for the treatment of acute forms of mastitis induced by Gram-positive bacteria.

Studies in laboratory animals (rats, rabbits) have not produced any evidence of a teratogenic, embryotoxic or maternotoxic effect associated with the use of marbofloxacin.
The safety of marbofloxacin has been demonstrated following treatment of animals with a daily dose of 2 mg/kg in pregnant cattle. Its safety has also been demonstrated in piglets and suckling calves when used in sows and cows.

Safety of the product at 8 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows. Use only according to the benefit/risk assessment by the responsible veterinarian.

No sign of overdose has been observed after administration of 3 times the recommended dose.
Overdoses exceeding this may cause signs in the form of acute neurological disorders which would have to 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 medical product or waste materials derived from such veterinary medical 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.

Local representative:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
pharmacovigilance.uk@krka.biz

Vm: 01656/4055
POM-V Prescription Only Medicine-Veterinarian

Approved: 20 December 2018