PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor 20 mg/ml solution for injection for cattle, pigs and dogs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of solution for injection contains 20 mg of Marbofloxacin

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

20 ml
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: SC, IV, IM
Pigs: IM
Dogs: SC, IV

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle (Pre-ruminant calves up to 100 kg body weight):
Meat and offal: 6 days

Pigs:
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

Vm 01656/4060

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor 20 mg/ml solution for injection for cattle, pigs and dogs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of solution for injection contains 20 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: SC, IM, IV
Pigs:IM
Dogs: SC, IV

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle (Pre-ruminant calves up to 100 kg body weight):
Meat and offal: 6 days

Pigs:
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 01656/4060

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor 20 mg/ml solution for injection for cattle, pigs and dogs
Marbofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

20 mg/ml

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

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC, IM , IV
Pigs: IM
Dogs: SC, IV

5. WITHDRAWAL PERIOD

Withdrawal period:
Cattle (Pre-ruminant calves up to 100 kg body weight):
Meat and offal: 6 days

Pigs:
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 FOR:
Quiflor 20 mg/ml solution for injection for cattle, pigs and dogs

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 20 mg/ml solution for injection for cattle, pigs and dogs

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

Each ml of solution for injection contains:

Active substance:
Marbofloxacin 20 mg

Excipients:
Metacresol 2 mg
Disodium edetate 0.10 mg
Monothioglycerol 0.50 mg

Clear, greenish yellow to brownish yellow solution.

4. INDICATION(S)

Cattle (pre-ruminant calves up to 100 kg b.w)
Treatment of respiratory infections caused by sensitive strains of *Mannheimia haemolytica, Pasteurella multocida* and *Mycoplasma bovis.*

Fattening pigs
Treatment of respiratory infections caused by sensitive strains of *Actinobacillus pleuropneumoniae, Pasteurella multocida* and *Mycoplasma hyopneumoniae.*

Dogs
Treatment of infected wounds (including drained subcutaneous abscesses) due to *Escherichia coli*, *Pasteurella* sp. and *Pseudomonas* sp.
Treatment of lower or urinary tract infections due to *Escherichia coli and Proteus* sp.

The veterinary medicinal 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.
Marbofloxacin should not be used in dogs aged less than 12 months or less than 18 months for exceptionally large breeds of dogs, such as Great Danes or mastiffs with a longer growth period.
Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

6. ADVERSE REACTIONS

In calves and pigs, administration by subcutaneous and intramuscular route may induce transitory oedema. Administration by the intramuscular route may cause pain reaction and inflammatory lesions at the site of injection. Inflammatory lesions persist 6 days in pigs and 12 days in calves.

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

7. TARGET SPECIES

Cattle (pre-ruminant calves up to 100 kg b.w).
Pigs.
Dogs.

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

Cattle:
The recommended dosage is 2 mg/kg/day (1 ml/10 kg) in a single daily injection by intramuscular or subcutaneous route (the first injection may also be given by intravenous route), for 3 to 5 days.

Pigs:
The recommended dosage is 2 mg/kg/day (1 ml/10 kg) by a single daily intramuscular injection, for 3-5 days.

Dogs:
Treatment of infected wounds (including drained subcutaneous abscesses): 2 mg/kg (1 ml/10 kg) by a single subcutaneous or intravenous injection on the first day of treatment, followed the next day by oral administration of marbofloxacin tablets once daily at a dosage of 2mg/kg for 6 days.
Treatment of infections of lower urinary tract: 2 mg/kg (1 ml/10 kg) by a single subcutaneous or intravenous injection on the first day of treatment, followed the next day by oral administration of marbofloxacin tablets once daily at a dosage of 2mg/kg for at least 10 days and up to 28 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

The dose volume given at one injection site should not exceed 6 ml in calves, and 3 ml in pigs.

In small dogs, a tuberculin or insulin syringe may be used to accurately dose the product.

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 (Pre-ruminant calves up to 100 kg body weight):
Meat and offal: 6 days
Pigs:
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 packaging 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)

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.

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.
The fluoroquinolones have been shown to induce erosion of articular cartilage in juvenile dogs and care should be taken to dose accurately especially in young animals.
The fluoroquinolones are also known for their potential neurological side effects. Cautious use is recommended in dogs diagnosed as suffering from epilepsy.

In cattle and pigs, 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, hypersalivation or trembling which should be treated symptomatically.
In dogs, after subcutaneous administration, no undesirable effect is observed up to 2 times the maximum recommended dose. After intravenous administration at 4 mg/kg, rare mild and transitory side effects have been reported:
- ptyalism (excess salivation)
- nervous disorders: vocalization, excitation, trembling (myoclonia).

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase. Fluoroquinolones may reduce the metabolism and exacerbate the nephrotoxicity of cyclosporine.
Fluoroquinolones may be used concurrently with tolfemic acid. In the absence of studies with other non-steroidal anti-inflammatory drugs, interactions cannot be excluded.

Studies carried out with laboratory animals showed no embryotoxic, foetotoxic or teratogenic effects.
May be used in pregnant and lactating cows and sows.
No specific studies have been carried out on pregnant bitches. In pregnant and lactating bitches, use only according to the benefit/risk assessment by the responsible veterinarian.

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

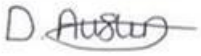
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Solution for injection is available in glass bottles of 20, 50, 100 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
Tel: 02071 646 156
pharmacovigilance.uk@krka.biz

Approved: 26 October 2017