PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbiflox 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.
Excipients: Metacresol, Disodium edetate, Monothioglycerol

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: SC or IM
Pigs (sows): IM

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
8 mg/kg single dose:
Meat and offal: 3 days
Milk: 72 hours
2 mg/kg single daily injection, for 3 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 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(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbiflox 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.
Excipients: Metacresol**,** Disodium edetate; Monothioglycerol

3. PHARMACEUTICAL FORM

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: SC or IM
Pigs (sows): IM

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
8 mg/kg single dose:
Meat and offal: 3 days
Milk: 72 hours
2 mg/kg single daily injection, for 3 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)

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Cattle: SC or IM
Pigs (sows): IM

5. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
8 mg/kg single dose:
Meat and offal: 3 days
Milk: 72 hours
2 mg/kg single daily injection, for 3 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 FOR:
Marbiflox 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

Marbiflox 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)

In cattle:
- treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia haemolytica*, and *Histophilus somni.*
- treatment of acute forms of mastitis induced by marbofloxacin-sensitive *Escherichia coli* strains, during lactation.

In pigs:
- treatment of the Metritis Mastitis Agalactia syndrome caused by marbofloxacin-sensitive bacterial strains.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Administration by the intramuscular route may cause transient local reactions such as pain or an oedema at the injection site and inflammatory reactions which may persist for at least 12 days after injection.

Fluoroquinolones are known to induce arthropathies. Nevertheless, this effect has never been observed with marbofloxacin in cattle.
In cattle and pigs, the prefered injection site is the neck area.

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.

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

Cattle:
Respiratory infections:
- *Intramuscular use:*
The recommended dosage is 8 mg/kg bodyweight i.e. 2 ml/25 kg bodyweight in a single injection.
If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.
Acute mastitis:
- *Intramuscular or subcutaneous use:*
The recommended dosage is 2 mg/kg i.e. 1 ml/50 kg bodyweight in a single daily injection, for 3 days.
The first injection may also be given by the intravenous route too.

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.

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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Cattle:
8 mg/kg single dose:
Meat and offal: 3 days
Milk: 72 hours
2 mg/kg single daily injection, for 3 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 labelafter {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)

Special precautions for use in animals
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 efficacy data showed that the product has insufficient efficacy for the treatment of acute forms of mastitis induced by gram-positive bacteria.

User Warnings
Wash hands after use.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the product.
In case of contact with skin or eyes, rinse with plenty of water.
Care should be taken to avoid accidental self injection.
In case of accidental self injection, seek medical advice and show the label to the doctor.
Accidental self-injection can induce a slight irritation.

Use during pregnancy, lactation or lay
Studies in laboratory animals (rats, rabbits) have not produced any evidence of a teratogenic, embryotoxic or maternotoxic effect with marbofloxacin.
The safety of marbofloxacin has been demonstrated at treatment of animal with daily dose 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.

Overdose (symptoms, emergency procedures, antidotes), if necessary
No sign of overdosage has been observed with the product after administration of 3 times the recommended dose.
Overdosage symptoms of marbofloxacin are acute neurological disorders that should be treated symptomatically.

Incompatibilities
Do not mix with other medicinal products.

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.