

**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 preferred 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 label 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)**

### **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.