PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubiflox 20 mg/ml solution for injection for cattle and pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

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

Distributor: Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4056
POM-V To be supplied only on veterinary prescription.

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubiflox 20 mg/ml solution for injection for cattle and pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 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

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(S)

Vm 01656/4056
POM-V To be supplied only on veterinary prescription.

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubiflox 20 mg/ml solution for injection for cattle and pigs
Marbofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

20 mg/ml

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle:SC, IM, IV
Pigs: IM

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
Ubiflox 20 mg/ml solution for injection for cattle and pigs

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

Ubiflox 20 mg/ml solution for injection for cattle and pigs
Marbofloxacin

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

1 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 *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma bovis.*

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

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 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.

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

The recommended dosage is 2 mg/kg/day (1 ml/10 kg) in a single daily injection by subcutaneous or intramuscular routes in cattle (the first injection may also be given by intravenous route), and by intramuscular route in pigs.
Treatment duration is as follows:
- cattle, IM, SC route: 3 to 5 days
- pigs, IM route: 3 to 5 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.

The cap may be safely punctured up to 20 times. The user should choose the most appropriate vial size according to the target species to treat.

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 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.

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.

Distributor: Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London EC4A 3AE

Vm 01656/4056

POM-V To be supplied only on veterinary prescription

Approved: 01 July 2016