PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROXIL 100 mg/ml solution for injection for cattle and pigs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of solution for injection contains:
Enrofloxacin 100 mg and n-butyl alcohol 30 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Cattle: iv. or sc.
Pigs: im.

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
Following intravenous injection: Meat and offal: 5 days. Milk: 3 days.
Following subcutaneous injection: Meat and offal: 12 days. Milk: 4 days.
Pigs: meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf-life after first opening the container: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the container in the outer carton.

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

Vm 01656/5067

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROXIL 100 mg/ml solution for injection for cattle and pigs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of solution for injection contains:
Enrofloxacin 100 mg and n-butyl alcohol 30 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Cattle: iv. or sc.
Pigs: im.

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
Following intravenous injection: Meat and offal: 5 days. Milk: 3 days.
Following subcutaneous injection: Meat and offal: 12 days. Milk: 4 days.
Pigs: meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf-life after first opening the container: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the container in the outer carton.

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

Vm 01656/5067

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROXIL 100 mg/ml solution for injection for cattle and pigs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of solution for injection contains:
Enrofloxacin 100 mg and n-butyl alcohol 30 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Cattle	Pig
100 kg BW ... 5 ml iv. or sc.	40 kg BW... 1 ml im.

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
Following intravenous injection:
Meat and offal: 5 days.
Milk: 3 days.
Following subcutaneous injection:
Meat and offal: 12 days.
Milk: 4 days.
Pigs: meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Shelf-life after first opening the container: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Keep the container in the outer carton.

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 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 01656/5067

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:

ENROXIL 100 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:
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

ENROXIL 100 mg/ml solution for injection for cattle and pigs
Enrofloxacin

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

1 ml of solution for injection contains 100 mg of enrofloxacin and 30 mg of n-butyl alcohol as antimicrobial preservative.

4. INDICATION(S)

Cattle:
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old.

Pigs:
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae.*
Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

5. CONTRAINDICATIONS

Do not use for prophylaxis.
Do not use in cases of resistance against quinolones.
Do not use in cases of disturbances in growth of cartilages and/or during injury of locomotory system particularly on functionally loaded joints or due to body weight loaded joints.
Do not use in animals with known hypersensitivity to enrofloxacin or other fluoroquinolones or to any of the excipients.
Do not use in growing horses because of possible deleterious damage on articular cartilage.

6. ADVERSE REACTIONS

Digestive tract disorders (e.g. diarrhoea) may occur in very rare cases. These signs are generally mild and transient.
In very rare cases intravenous treatment of cattle can cause shock reactions, presumably as a result of circulatory impairment.
Local reactions at injection site
In pigs, after intramuscular administration of the product, inflammatory reactions may occur. They may persist up to 28 days after the injection.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

7. TARGET SPECIES

Cattle, pigs

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

Intravenous, subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.

Cattle:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old*:* 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 5 days.
The product can be administered by slow intravenous or subcutaneous administration.
Acute mastitis caused by *Escherichia coli*: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, by slow intravenous injection once daily for two consecutive days.

The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.
Cattle: Not more than 10 ml should be administered at one subcutaneous injection site.
Calves: Not more than 5 ml should be administered at one subcutaneous injection site.

Pigs:
2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/20 kg bw, once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw,
corresponding to 1 ml/20 kg bw, once daily by intramuscular injection for 3 days.
In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

If there is no clinical improvement within two to three days, further susceptibility testing and possibly a change in antimicrobial therapy should be considered.

9. ADVICE ON CORRECT ADMINISTRATION

Normal sterile precautions should be taken.
To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD

Cattle:
Following intravenous injection:
Meat and offal: 5 days.
Milk: 3 days.
Following subcutaneous injection:
Meat and offal: 12 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Keep the container in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after {EXP}.
Shelf-life after first opening the container: 28 days.
When the container is broached for the first time, using the in-use shelf life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

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 including use deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to enrofloxacin and may decrease the effectiveness of treatment with all fluoroquinolones due to the potential for cross-resistance.

Treatment should not be repeated if an allergic reaction occurs.

Enrofloxacin is partially excreted through the kidney. In case of the kidney's functional failure slower excretion should be taken into account.

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.

For animal treatment only.

Do not exceed the recommended dose.

The cap may be safely punctured up to 40 times. When treating groups of animals, use a draw-off needle.

Only the 50 ml vial should be used to treat small piglets.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to fluoroquinolones should avoid any contact with the product.

Avoid skin and eye contact. Wash any splashes from skin or eyes immediately with water.

Wash hands after use. Do not eat, drink or smoke whilst handling the product.

Care should be taken to avoid accidental self-injection. If accidental self-injection occurs seek medical advice immediately.

Other precautions

In countries where feeding of fallen stock to scavenger bird populations is permitted as a conservation measure (see Commission Decision 2003/322/EC), the possible risk to hatching success should be considered before feeding carcasses of livestock recently treated with this product.

Use during pregnancy and lactation

Cattle : The safety of enrofloxacin has been established in pregnant cows during the 1st quarter of pregnancy. The product can be used in pregnant cows during the 1st quarter of pregnancy. The use of the product in cows during the 3 last quarters of pregnancy should be based on a benefit-risk assessment by the responsible veterinarian. The product can be used in cows during lactation.

Pigs: The safety of the veterinary medicinal product has not been established during pregnancy. Use only accordingly to the benefit-risk assessment by the responsible veterinarian. The product can be used in sows during lactation.

Interaction with other medicinal products and other forms of interaction:
When combined with tetracyclines and macrolide antibiotics, enrofloxacin may produce an antagonistic effect.
Do not use concurrently with theophylline as the elimination of theophylline may be delayed.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes):
In cases of accidental overdoses digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.
In pigs, no adverse effects were reported after the administration of 5 times the recommended dose.
In cattle, overdose has not been documented.
In accidental overdose there is no antidote and treatment should be symptomatic.

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

Bottle of 50 and 100 ml.

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

POM-V

Approved: 26 October 2017