PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enroxil 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 100 mg of enrofloxacin.

Excipients:
n-butyl alcohol 30 mg/ml

3. PACKAGE SIZE

50ml
100 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Cattle: **i.v., s.c.**
Pigs: **i.m.**

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle:
i.v.: Meat and offal: 5 days. Milk: 3 days.
s.c.: Meat and offal: 12 days. Milk: 4 days.
Pigs: meat and offal: 13 days

8. EXPIRY DATE

Exp. {month/year}
Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE«

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/5067

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND SAFE USE IF APPLICABLE

POM-V

Veterinary medicinal product subject to prescription

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enroxil 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 100 mg of enrofloxacin.

Excipients:
n-butyl alcohol 30 mg/ml

50 ml
100 ml

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

Cattle	Pig
100 kg BW ... 5 ml i.v. or s.c.	40 kg BW... 1 ml i.m.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle:
i.v.:
Meat and offal: 5 days.
Milk: 3 days.
s.c.:
Meat and offal: 12 days.
Milk: 4 days.
Pigs: meat and offal: 13 days

6. EXPIRY DATE

Exp {month/year}
Once opened use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V
(Veterinary medicinal product subject to prescription)

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enroxil 100 mg/ml solution for injection for cattle and pigs

2. COMPOSITION

Each ml contains:

Active substance:
Enrofloxacin 100 mg

Excipients:
n-butyl alcohol 30 mg

Clear yellow solution practically free from particles.

3. TARGET SPECIES

Cattle and pigs.

4. INDICATIONS FOR USE

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 growing horses because of possible deleterious damage on articular cartilage.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. SPECIAL WARNINGS

Special precautions for safe use in the target species:
Official and local antimicrobial policies should be taken into account when the veterinary medicinal 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 veterinary medicinal 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.
Do not re-inject into the same injection site.
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 veterinary medicinal 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 veterinary medicinal product.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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 veterinary medicinal product.

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

Lactation:
Can be used during lactation.

Interactions with other medicinal products and other forms of interaction:
Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e. g. macrolides, tetracyclines or phenicols).
Do not use concurrently with theophylline as the elimination of theophylline may be delayed.

Overdose:
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.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. ADVERSE EVENTS

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (e.g. diarrhoea)[1] Circulatory shock[2] Injection site reaction

[1] Generally mild and transient.
[2] Following intravenous administration.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (e.g., diarrhoea)[1]
Undetermined frequency (cannot be estimated from the available data):	Injection site inflammation[2]

[1] Generally mild and transient.
[2] May persist up to 28 days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {https://www.gov.uk/report-veterinary-medicine-problem}.

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

Intravenous (cattle), subcutaneous (cattle) or intramuscular (pigs) use.
Repeated injections should be made at different injection sites.
To ensure a correct dosage, body weight should be determined as accurately as possible.

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 veterinary medicinal 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.

Do not exceed the recommended dose.

9. ADVICE ON CORRECT ADMINISTRATION

Normal sterile precautions should be taken.

10. WITHDRAWAL PERIODS

Cattle
Intravenous use:
Meat and offal: 5 days.
Milk: 3 days.
Subcutaneous use:
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 bottle in the outer carton.

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 PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISTION NUMBERS AND PACK SIZES

Vm 01656/5067

Cardboard box with one 50 ml or 100 ml bottle.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

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

Local representatives and contact details to report suspected adverse reactions:
KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
info.uk@krka.biz

17. OTHER INFORMATION

POM – V
Veterinary medicinal product subject to prescription.

For animal treatment only.

Approved 18 May 2024