# ANNEX II

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**BOX**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enroxil 50 mg/ml solution for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 mg of enrofloxacin.

## 3. PACKAGE SIZE

50 ml
100 ml

## 4. TARGET SPECIES

Cattle (calves), pigs and dogs

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Calves: **i.v., s.c.**
Pigs: **i.m.**
Dogs: **s.c.**

## 7. WITHDRAWAL PERIODS

Withdrawal period:
Calves:
i.v.: Meat and offal: 5 days.
s.c.: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.
Pigs: meat and offal: 13 days

## 8. EXPIRY DATE

Exp. {mm/yyyy}
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, d.d., Novo mesto

## 14. MARKETING AUTHORISATION NUMBERS

Vm 01656/3068

## 15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**LABEL**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enroxil 50 mg/ml solution for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 mg of enrofloxacin.

50 ml
100 ml

## 3. TARGET SPECIES

Cattle (calves), pigs and dogs

## 4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

| Calf | Pig | Dog |
|---|---|---|
| 100 kg BW... 10 ml<br>i.v. or s.c. | 20 kg BW... 1 ml<br>i.m. | 10 kg BW ... 1 ml<br>s.c. |

## 5. WITHDRAWAL PERIODS

Withdrawal period:
Calves:
i.v.: Meat and offal: 5 days.
s.c.: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.
Pigs: meat and offal: 13 days

## 6. EXPIRY DATE

Exp. {mm/yyyy}
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, d.d., Novo mesto

## 9. BATCH NUMBER

Lot {number}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Enroxil 50 mg/ml solution for injection for calves, pigs and dogs

## 2. Composition

Each ml contains:

**Active substance:**
Enrofloxacin 50 mg

**Excipients:**
n-butyl alcohol 30 mg

Clear yellow solution practically free from particles.

## 3. Target species

Cattle (calves), pigs and dogs.

## 4. Indications for use

Calves:
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* 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*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*.

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

Dogs:
Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of *Staphylococcus*

spp., *Escherichia coli*, *Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

## 5. Contraindications

Do not use for prophylaxis.
Do not use in case of resistance against quinolones.
Do not use in case 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 young dogs during their growth, i.e. in small breeds of dogs less than 8 months of age, in big breeds of dogs less than 12 months of age, in giant breeds of dogs less than 18 months of age, as articular cartilage may be affected during the period of growth.
Do not use in growing horses because of possible deleterious damage on articular cartilage.
Do not use in animals that are epileptic or suffer from seizures since enrofloxacin may cause CNS stimulation.
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 the case of the kidney's functional failure slower excretion should be taken into account. Special caution should be taken when using enrofloxacin in animals with impaired renal function.
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 dogs and 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 and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects but have shown evidence of foetotoxic effects at maternotoxic doses.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

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.
Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the $C_{max}$ of enrofloxacin.

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 dogs and 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

Calves:

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

[1] Generally mild and transient.
[2] May persist up to 14 days.

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.

Dogs:

| | |
|---|---|
| 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 reaction (e. g. oedema (swelling))[2] |

[1] Generally mild and transient.
[2] Moderate and transient.

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: {national system details}.

## 8. Dosage for each species, routes and method of administration

Intravenous (calves), subcutaneous (calves, dogs) 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.

Calves:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.
The veterinary medicinal product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at one subcutaneous injection.

Pigs:
2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/10 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/10 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.

Dogs:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable veterinary medicinal product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the SPC of the tablet veterinary medicinal product.
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

Calves
Intravenous use:
Meat and offal: 5 days.
Subcutaneous use:
Meat and offal: 12 days.

Not authorised for use in animals producing milk for human consumption.

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 or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. 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 authorisation numbers and pack sizes

Cardboard box with one 50 ml or 100 ml bottle.

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

February 2024

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

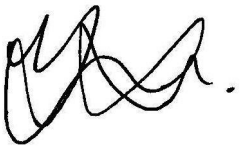
Marketing authorisation holder and contact details to report suspected adverse reactions:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

## 17. Other information



Approved: 11 May 2024