PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROXIL 100 mg/ml oral solution for chickens and turkeys
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of oral solution contains:

Enrofloxacin	100 mg
Preservative: Benzyl alcohol	14 mg

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Chickens and turkeys

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

In drinking water use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Chickens: Meat and offal: 7 days
Turkeys: Meat and offal: 13 days
Not authorised for use in laying birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Operator Warnings:
Gloves should be worn when handling this product. Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke while using this product.
Wash hands and exposed skin after use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by...

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.

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 01656/4021

17. MANUFACTURER'S BATCH NUMBER

Lot {number}:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROXIL 100 mg/ml oral solution for chickens and turkeys
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of oral solution contains:

Enrofloxacin	100 mg
Preservative: Benzyl alcohol	14 mg

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Chickens and turkeys

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

In drinking water use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Chickens: Meat and offal: 7 days
Turkeys: Meat and offal: 13 days
Not authorised for use in laying birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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 01656/4021

17. MANUFACTURER'S BATCH NUMBER

Lot {number}:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROXIL 100 mg/ml oral solution for chickens and turkeys
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of oral solution contains:

Enrofloxacin	100 mg
Preservative: Benzyl alcohol	14 mg

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

1000 ml

5. TARGET SPECIES

Chickens and turkeys

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

In drinking water use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Chickens: Meat and offal: 7 days
Turkeys: Meat and offal: 13 days
Not authorised for use in laying birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by…

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.

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 01656/4021

17. MANUFACTURER'S BATCH NUMBER

Lot {number}:

PACKAGE LEAFLET FOR
ENROXIL 100 mg/ml oral solution for chickens and turkeys

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROXIL 100 mg/ml oral solution for chickens and turkeys
Enrofloxacin

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

1 ml of oral solution contains 100 mg of enrofloxacin. Also contains 14 mg of benzyl alcohol as preservative.

4. INDICATION(S)

Treatment of infections caused by the following bacteria susceptible to enrofloxacin:

Chickens
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida.

Turkey
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida.

5. CONTRAINDICATIONS

Do not use for prophylaxis.
Do not use when resistance / cross-resistance to (fluoro)quinolones is known to occur in the flock intended for treatment.
Infections caused by *Streptococcus* spp., because of only marginal susceptibility to enrofloxacin.
Do not use in other animals.

Do not use in case of hypersensitivity to the active substance, or to any of the excipients.

6. ADVERSE REACTIONS

Locomotion disturbances as a result of damage of joint cartilage could not be excluded in case that fluoroquinolones are used during the growing period, particularly at higher temperatures, when consumption of medicated water is drastically increased for longer period.

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

7. TARGET SPECIES

Broilers, broiler breeders, replacement chickens, turkeys.

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

Dosage:
Chickens and turkeys
10 mg enrofloxacin/kg bodyweight per day for 3–5 consecutive days.

Treatment for 3–5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms. If no clinical improvement is achieved within 2–3 days, alternative antimicrobial therapy should be considered based on susceptibility testing. The uptake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of Enroxil should be adjusted accordingly. Taking into consideration that 10 mg enrofloxacin per kg body weight corresponds to 0.1 ml of Enroxil per kg body weight, the following calculation should be made to provide the required amount of Enroxil per litre of drinking water:

$$\frac{\text{ml Enroxil per kg bodyweight daily} \times \text{average bodyweight (kg) of the animals to be treated} \times \text{number of animals}}{\text{Total water consumption (l) of the flock at the previous day}} = \text{ml Enroxil per litre drinking water}$$

Care should be taken that the intended dose is completely ingested.

Enroxil oral solution 100 mg/ml is administered via the drinking water. Medicated water should be freshly prepared every day, immediately prior to provision. Medication of the water supply should be continuous during the treatment period and no other source of water should be available.

9. ADVICE ON CORRECT ADMINISTRATION

Enroxil oral solution 100 mg/ml may be put directly into the header tank or introduced via a water proportioner pump. For the preparation of the medicated water for small groups of animals the measuring cup included with the packaging should be used.
During preparation of medicated water, the product should be admixed into water and not the other way round.
Only sufficient medicated drinking water should be prepared to cover the daily requirements.
Medicated drinking water should be replaced every 24 hours.

After the end of treatment, the watering system should be cleaned appropriately to prevent the intake of remaining, subtherapeutic doses of the drug, which may lead to resistance.

10. WITHDRAWAL PERIOD

Chickens: Meat and offal: 7 days.
Turkeys: Meat and Offal: 13 days.

Not authorised for use in laying birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

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 use this veterinary medicinal product after the expiry date stated on the label.

Shelf-life after first opening the immediate packaging: 28 days
Shelf-life after dilution: 24 hours.

When the container is opened for the first time, using the in-use shelf-life, 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)

For animal treatment only.

Treatment of *Mycoplasma* spp infections may not eradicate the organism.
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.
Since enrofloxacin was first authorised for use in poultry, there has been widespread reduction in susceptibility of *E. coli* to fluoroquinolones and emergence of resistant organisms. Resistance has also been reported in *Mycoplasma synoviae* in the EU.
As enrofloxacin will be partly excreted via the kidneys, elimination will be delayed in cases with kidney disorders.
After the end of treatment, the watering system should be cleaned appropriately to prevent the intake of remaining subtherapeutic doses of the drug, which may lead to resistance.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
When combined with tetracyclines and macrolide antibiotics, enrofloxacin may produce an antagonistic effect.
Resorption of enrofloxacin may be reduced, when it is combined with substances containing magnesium or aluminium.
Increased influx of the air (admixing CO_2 from the air) into medicated drinking water may result in precipitation of enrofloxacin.
Precipitation of the salt of enrofloxacin and alkalis may occur at higher concentration of calcium and magnesium in the water system during intermediate dilution in the dosage devices.
Do not combine enrofloxacine with non steroidal antiinflammatories.
Due to the low toxicity of enrofloxacin, the danger of overdosing is limited. In cases of significant overdose, transient reduction in mobility and cramps may occur. Symptomatic treatment is recommended in such cases.

User warnings
Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product. Wash any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not eat, drink or smoke while using the product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed.

15. OTHER INFORMATION

To be supplied only on veterinary prescription.

Pack sizes:
100 ml
1000 ml.
Not all pack sizes may be marketed.

Approved: 27 June 2018