Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrox 100 mg/ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

1 ml of oral solution contains:

Enrofloxacin	100	mg.

Excipients

Benzyl alcohol	14	mg.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (broilers, broiler breeders, replacement chickens), turkeys.

4.2 Indications for use, specifying the target species

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

Chickens

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

Turkeys

Mycoplasma gallisepticum,

Mycoplasma synoviae,
Pasteurella multocida.

4.3 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.
Do not use in poultry producing eggs for human consumption.
Do not use in aquatic poultry.
Do not use in infections caused by *Streptococcus* spp., because of only marginal susceptibility to enrofloxacin.

4.4 Special warnings for each target species

Treatment of *Mycoplasma* spp. infections may not eradicate the organism.

4.5 Special precautions for use

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 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 the fluoroquinolones and emergence of resistant organisms. Resistance has also been reported in *Mycoplasma synoviae* in the EU.
Enrofloxacin is partially excreted through the kidney. In cases of renal failure excretion of the active substance may be slowed.
Use of veterinary medicinal product in poultry must comply with Regulation EC 1177/2006 of the Commission and the transposing national regulations.

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

Wear impervious gloves when handling the 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.

People with known hypersensitivity to enrofloxacin should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Disturbances in locomotion as a result of damage to joint cartilage cannot be excluded if fluoroquinolones are used during the growing period, particularly at higher temperatures, when consumption of medicated water is drastically increased for longer period.

4.7 Use during pregnancy, lactation or lay

Do not use in laying birds producing eggs for human consumption, see 4.11.

4.8 Interaction with other medicinal products and other forms of interactions

Concurrent use of enrofloxacin with other antimicrobials, tetracyclines and macrolide antibiotics, may result in antagonistic effects.

4.9 Amounts to be administered and administration route

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.

Via the drinking water. Always make sure that the entire dose offered has been consumed. The
medicated water should be made up fresh each day just before it is offered to the animals. The
drinking water must be medicated throughout the treatment period, and no other water source should
be available. Determine the bodyweight of the birds as accurately as possible in order to avoid
underdosing.

Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be

checked constantly to assure proper medication. Empty the water system and fill it with medicated
water before starting the treatment.

Calculate the daily quantity (ml) of the product required for treatment period as follows:
Total number of birds x Average body weight in kg x 0.1 = Total volume (ml) per day
The product may be put directly into the header tank or introduced via a water proportioner pump.
Care should be taken that the intended dose is completely ingested.
Use appropriate and properly calibrated dosing equipment.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Fluoroquinolone
ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

Enrofloxacin is a synthetic, broad spectrum antimicrobial, bactericidal in action and effective against a wide range of gram positive and gram negative bacteria as well as mycoplasmas**.** It inhibits the enzyme DNA-gyrase in the cell nuclei during replication of bacterial DNA. It also acts on bacterial cells during stationary phase by changing the permeability in the phospholipid cellular membranes.
Antibacterial spectrum

Enrofloxacin is active against many Gram-negative bacteria, against Gram-positive bacteria and *Mycoplasma* spp. In vitro susceptibility has been shown in strains of (i) Gram-negative species such as *Pasteurella multocida* and *Avibacterium (Haemophilus) paragallinarum* and (ii) *Mycoplasma gallisepticum* and *Mycoplasma synoviae*. (See section 4.5).

Types and mechanisms of resistance

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective
enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced
susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

5.2 Pharmacokinetic particulars

The pharmacokinetics of enrofloxacin are such that both oral and parenteral administration lead to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than that found in the serum have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid and the aqueous humour.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Hydoxypropylmethylcellulose
Potassium hydroxideWater, purified

6.2 Major incompatibilities

None known. Do not mix with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life after first opening the container: 3 months
Shelf-life after dilution or reconstitution: 24 hours

6.4 Special precautions for storage

The veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 glass vial of 100 ml and measuring cup.
Polyethylene bottle of 1 litre and measuring cup.

Polyethylene bottle of 5 litres.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10774/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of last renewal: 9th September 2010

10 DATE OF REVISION OF THE TEXT

July 2018