[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enro-Sleecol 100 mg/ml oral solution for chickens and turkeys (DE)
Enroshort 100 mg/ml oral solution for chickens and turkeys (BE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Enrofloxacin 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	14 mg
Hypromellose	
Potassium Hydroxide	
Water, Purified	

Clear, yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens and turkeys.

3.2 Indications for use for each 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.

3.3 Contraindications

Do not use when resistance/ cross-resistance to (fluoro)quinolones is known to occur in the flock intended for treatment.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

Before use, header tanks should be emptied, thoroughly cleaned and then filled with a known volume of clean water before adding the required amount of the veterinary medicinal product. The resulting mixture should be stirred.
Before use, header tanks should be inspected at regular intervals for presence of dust, algae formation and sedimentation.
Do not use for prophylaxis.
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 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.
If there is no clinical improvement within two to three days susceptibility testing should be repeated and therapy should be changed, if appropriate.
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.

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

Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions.
Wash any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
None.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent use of enrofloxacin with other antimicrobials, tetracyclines and macrolide antibiotics, may result in antagonistic effects.
Absorption of enrofloxacin may be reduced if the veterinary medicinal product is administered together with substances containing magnesium or aluminium.
Do not combine enrofloxacin with steroidal anti-inflammatory veterinary medicinal products.

3.9 Administration routes and 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.

In drinking water use. Medication of the water supply should be continuous during the treatment period and no other source of water should be available.

Medicated water should be made every day, immediately prior to provision. Carefully calculate the total body mass to be treated and the total daily water consumption before each treatment.
The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of enrofloxacin may need to be adjusted accordingly. Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.1 \times \text{Average bodyweight of birds to be treated (kg)} \times \text{Number of birds}}{\text{Total water consumption (l) of the flock at the previous day}} = \text{ml veterinary medicinal product per liter of drinking water}$$

Care should be taken that the intended dose is completely ingested.
The veterinary medicinal product may be put directly into the header tanks, or via water proportioner systems. The use of suitably calibrated measuring equipment is recommended

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

Do not use within 2 weeks before the start of the laying period.

Not for use in birds producing or intended to produce eggs for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA90

4.2 Pharmacodynamics

Enrofloxacin is bactericidal in action with activity against Gram positive and Gram negative bacteria and mycoplasmas. The mechanism of action of the quinolones is unique among antimicrobials - they act primarily to inhibit bacterial DNA gyrase, an enzyme responsible for controlling the supercoiling of bacterial DNA during replication. Resealing of the double standard helix is inhibited resulting in irreversible degradation of the chromosomal DNA. The fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

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 3.5)

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.

4.3 Pharmacokinetics

The pharmacokinetics of enrofloxacin is such that oral and parenteral administration leads 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, skin, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid and the aqueous humour.
The degree of metabolism depends on the species and ranges between 50-60%. Biotransformation at hepatic level of enrofloxacin results in the active metabolite, ciprofloxacin. In general, metabolism is by hydroxylation and oxidation processes to oxofluoroquinolones. Other reactions that also occur are N-dealkylation and conjugation with glucoronic acid.
Excretion occurs by biliary and renal route, with excretion in the urine predominating.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution or reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

100 ml amber type III glass vial with polypropylene measuring cup in carton.
1000 ml high density polyethylene bottle and polypropylene measuring cup.

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box 100 ml
Bottle 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enro-Sleecol 100 mg/ml oral solution (DE)
Enroshort 100 mg/ml oral solution (BE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 100 mg of enrofloxacin.

3. PACKAGE SIZE

100 ml
1000 ml

4. TARGET SPECIES

Chickens and turkeys

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.

Do not use within 2 weeks before the start of the laying period.
Not for use in birds producing or intended to produce eggs for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once diluted use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

Marketing authorisation holder:

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enro-Sleecol 100 mg/ml oral solution (DE)
Enroshort 100 mg/ml oral solution (BE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 100 mg of enrofloxacin.

100 ml

3. TARGET SPECIES

Chickens and turkeys

4. ROUTES OF ADMINISTRATION

In drinking water use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.

Do not use within 2 weeks before the start of the laying period.
Not for use in birds producing or intended to produce eggs for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once diluted use within 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Enro-Sleecol 100 mg/ml oral solution for chickens and turkeys (DE)
Enroshort 100 mg/ml oral solution for chickens and turkeys (BE)

2. Composition

Each ml contains:

Active substance:
Enrofloxacin 100 mg

Excipients:
Benzyl alcohol 14 mg

Clear, yellow solution.

3. Target species

Chickens and turkeys.

4. Indications for use

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.

5. Contraindications

Do not use when resistance/ cross-resistance to (fluoro)quinolones is known to occur in the flock intended for treatment.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

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

Special precautions for safe use in the target species:
Before use, header tanks should be emptied, thoroughly cleaned and then filled with a known volume of clean water before adding the required amount of the veterinary medicinal product. The resulting mixture should be stirred.
Before use, header tanks should be inspected at regular intervals for presence of dust, algae formation and sedimentation.
Do not use for prophylaxis.
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 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.
If there is no clinical improvement within two to three days susceptibility testing should be repeated and therapy should be changed, if appropriate.
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions.
Wash any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the veterinary medicinal product.

Laying birds:
None.

Interaction with other medicinal products and other forms of interaction:
Concurrent use of enrofloxacin with other antimicrobials, tetracyclines and macrolide antibiotics, may result in antagonistic effects.
Absorption of enrofloxacin may be reduced if the veterinary medicinal product is administered together with substances containing magnesium or aluminium.
Do not combine enrofloxacin with steroidal anti-inflammatory veterinary medicinal products.

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

7. Adverse events

None.

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}*[listed in Appendix I*]*>.

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

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.

In drinking water use.

Medicated water should be made every day, immediately prior to provision. Carefully calculate the total body mass to be treated and the total daily water consumption before each treatment.
The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of enrofloxacin may need to be adjusted accordingly. Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.1 \times \text{Average bodyweight of birds to be treated (kg)} \times \text{Number of birds}}{\text{Total water consumption (l) of the flock at the previous day}} = \text{ml veterinary medicinal product per liter of drinking water}$$

Care should be taken that the intended dose is completely ingested.
The use of suitably calibrated measuring equipment is recommended

9. Advice on correct administration

The veterinary medicinal product may be put directly into the header tanks, or via water proportioner systems.
Medication of the water supply should be continuous during the treatment period and no other source of water should be available.

10. Withdrawal periods

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

Do not use within 2 weeks before the start of the laying period.
Not for use in birds producing or intended to produce eggs for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

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

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: 3 months.
Shelf life after dilution or reconstitution according to directions: 24 hours.

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

100 ml amber type III glass vial with polypropylene measuring cup in carton.
1000 ml high density polyethylene bottle and polypropylene measuring cup.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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>