SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
ENROCIN 10% Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active substance: Enrofloxacin 100.0 mg/ml
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Concentrate for oral solution.

4. CLINICAL PARTICULARS
4.1 Target species
Chicken and turkey.

4.2 Indications for use, specifying the target species
ENROCIN 10% Oral Solution is recommended for oral administration in the treatment of respiratory, intestinal and systemic infections caused by enrofloxacin sensitive organisms in poultry. Major indications include:
* chronic respiratory disease (*Mycoplasma gallisepticum, E. coli*)
* airsacculitis (*Mycoplasma meleagridis*)
* infectious synovitis (*Mycoplasma synoviae*)
* colibacillosis (*E. coli*)
* salmonelloses (*Salmonella spp.*)
* fowl cholera (*Pasteruella multocida*)
* turkey bordetellosis (*Bordetella avium*)
* infectious coryza (*Haemophilus paragallinarum*)
* erysipelas (*Erysipelothrix rhusiopathiae*)
* staphylococcosis (*Staphylococcus aureus*)
* chlamydiosis (*Chlamydia psittaci*)

4.3 Contraindications
Not for use in laying poultry.

4.4 Special warnings for each target species
None applicable.

4.5 Special precautions for use
Special precautions for use in animals
No special precautions are required.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Persons with known hypersensitivity to quinolones should avoid any contact with the product.
In order to avoid irritation of skin and/or eyes, use gloves and a face-protecting device when handling this product.

4.6 Adverse reactions (frequency and seriousness)
ENROCIN 10% is of low toxicity and side-effects are very rarely encountered. If suspected adverse reactions do occur, treatment should be discontinued. During the toxicological examinations no undesirable effects were detected.

4.7 Use during pregnancy, lactation or lay
Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

No major undesirable interactions of enrofloxacin as the active substance of the drug product with other medicaments are known.

4.9 Amounts to be administered and administration route

ENROCIN 10% Oral Solution must be administered daily via the drinking water in such a concentration that ensures the daily intake of 10 mg enrofloxacin per kg of body weight. The administration must be continued for 3-5 days.

Taking into account the 10% content of enrofloxacin in the bottle, the following calculation can be used as a guide to determine the quantity in ml to be added per 1000 litres of water:

$$\frac{\text{number of animals in the house x mean weight of individual animal (kg) x 100}}{\text{total water consumption of the house at the previous day (litres)}}$$

The solution should be prepared freshly each day.

No other of drinking water should be available during the medication period.

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

Overdosage of ENROCIN 10% may very rarely occurs because of good tolerance by the species to be used in. In the tolerance studies, the product failed to induce any toxic effect even when administered at a dosage of three times the recommended for two times (10 days) the recommended duration.

If suspected toxic reactions do occur due to extreme overdosage, the medication should be discontinued and appropriate symptomatic treatment should be performed if necessary.

4.11 Withdrawal period(s)

Edible tissues of chickens and turkeys: 3 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: quinolone antimicrobials. ATC vet code: QJ01MA90

Pharmacodynamic properties

Enrofloxacin is a bactericidal agent which inhibits the replication of bacteria by action on the functioning of the DNA-gyrase. It has an excellent *in vitro* activity against a wide range of aerobic Gram-negative bacteria including the *Enterobacteriaceae*, *Pasteurella spp*., *Haemophilus spp*. and *Actinobacillus spp*. It is also active against *Mycoplasma spp*., *Chlamydia spp*., *Brucella spp., Bordetella bronchispetica, Pseudomonas aeruginosa* and several Gram-positive bacteria, as well. The MIC_{90} of enrofloxacin against the commonest poultry pathogens (*E. coli*, *Salmonella spp*., *Pasteurella spp*. and *Mycoplasma spp*.) is generally ≤ 0.10 μg/ml.

Pharmacokinetic properties

Pharmacokinetics of enrofloxacin in laboratory animals is characterized by a rapid and extensive absorption from the gastrointestinal tract, a widespread distribution providing high tissue concentrations, a relatively low level of protein binding, a partial metabolism and an excretion by the kidneys and the faeces mainly in active form. The elimination half-live of enrofloxacin is short in each laboratory species, ranging from 1.5 to 2.5 hours. The main metabolite of enrofloxacin is ciprofloxacin which is antimicrobially active and is considered an important contributor to the activity of enrofloxacin. In dogs and cats, cirpofloxacin makes up about 20% of the total amount of enrofloxacin in the serum at any time. Since ciprofloxacin has been widely used in the human medicine for several years, its pharmacological and toxicological features are well-known and adequately published.

Pharmacokinetics of enrofloxacin in chickens and turkeys has been investigated in several studies. Results obtained from these studies indicate that enrofloxacin is rapidly absorbed from the gastrointestinal tract with peak serum concentrations within 2 hours after administration.

Bioavailability was reported between 64 and 89%. Following absorption, enrofloxacin is extensively distributed resulting in tissue concentrations markedly exceeding the plasma levels. In poultry, enrofloxacin concentrations in the lungs are usually 1.5-2 times the corresponding plasma levels. Enrofloxacin is partially metabolized in the liver. In chickens and turkeys, the plasma and tissue concentrations of ciprofloxacin as the main metabolite is low, with the exception of the excretory organs.
The continuous administration of enrofloxacin in the drinking water at a daily dose of 10 mg/kg was seen to produce efficacious concentrations in plasma and tissues in both target species.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium hydroxyde, Disodium edetate, Benzyl alcohol

6.2 Incompatibilities

None.

6.3 Shelf life

Shelf-life from date of manufacture: 2 years.
Shelf-life after first opening of container: 3 months.
Shelf-life after reconstitution in drinking water: 24 hours.

6.4. Special precautions for storage

Store between 15 and 25°C. Protect from light. Close container securely after use.
Keep out of the reach of children.

6.5 Nature and composition of immediate packaging

ENROCIN 10% Oral Solution is available in plastic bottles with a screw cap containing 1000 ml.

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

No additional precautions required.

7. MARKETING AUTHORISATION HOLDER

Lavet Pharmaceuticals Ltd.
1161 Budapest
Ottó u. 14.
Hungary

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1000 ml in plastic bottles with a screw cap

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocin 10% oral solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Enrofloxacin 100 mg/ml
Excipients: Potassium hydroxyde, Disodium edetate, Benzyl alcohol

3. PHARMACEUTICAL FORM

Concentrate for oral solution.

4. PACKAGE SIZE

1000 ml

5. TARGET SPECIES

Chickens and turkeys.

6. INDICATION(S)

* chronic respiratory disease (*Mycoplasma gallisepticum, E. coli*)
* airsacculitis (*Mycoplasma meleagridis*)
* infectious synovitis (*Mycoplasma synoviae*)
* colibacillosis (*E. coli*)
* salmonelloses (*Salmonella spp.*)
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* erysipelas (*Erysipelothrix rhusiopathiae*)
* staphylococcosis (*Staphylococcus aureus*)
* chlamydiosis (*Chlamydia psittaci*)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration via the drinking water.

8. WITHDRAWAL PERIOD

Edible tissues of chickens and turkeys: 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Persons with known hypersensitivity to quinolones should avoid any contact with the product.
In order to avoid irritation of skin and/or eyes, use gloves and a face-protecting device when handling this product.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store between 15 and 25ºC, protect from light.

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

No additional precautions required.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Lavet Pharmaceuticals Ltd.
1161 Budapest
Ottó u. 14.
Hungary

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PACKAGE LEAFLET FOR:
Enrocin 10% oral solution

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

Marketing authorization holder: Lavet Pharmaceuticals Ltd., 1161 Budapest, Ottó u. 14., Hungary
Manufacturer responsible for batch release: Lavet Pharmaceuticals Ltd., 2143 Kistarcsa, Batthyány u. 6., Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocin 10%

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

Active substance: Enrofloxacin 100 mg/ml
Excipients: Potassium hydroxyde, Disodium edetate, Benzyl alcohol

4. INDICATION(S)

ENROCIN 10% Oral Solution is recommended for oral administration in the treatment of respiratory, intestinal and systemic infections caused by enrofloxacin sensitive organisms in poultry. Major indications include:

* chronic respiratory disease (*Mycoplasma gallisepticum, E. coli*)
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* staphylococcosis (*Staphylococcus aureus*)
* chlamydiosis (*Chlamydia psittaci*)

5. CONTRAINDICATIONS

Not for use in laying poultry.

6. ADVERSE REACTIONS

ENROCIN 10% is of low toxicity and side-effects are very rarely encountered. If suspected adverse reactions do occur, treatment should be discontinued. During the toxicological examinations no undesirable effects were detected.

7. TARGET SPECIES

Chicken and turkey.

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

ENROCIN 10% Oral Solution must be administered daily via the drinking water in such a concentration that ensures the daily intake of 10 mg enrofloxacin per kg of body weight. The administration must be continued for 3-5 days.

9. ADVICE ON CORRECT ADMINISTRATION

ENROCIN 10% Oral Solution must be administered daily via the drinking water in such a concentration that ensures the daily intake of 10 mg enrofloxacin per kg of body weight. The administration must be continued for 3-5 days.

Taking into account the 10% content of enrofloxacin in the bottle, the following calculation can be used as a guide to determine the quantity in ml to be added per 1000 litres of water:

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The solution should be prepared freshly each day.
No other of drinking water should be available during the medication period.

10. WITHDRAWAL PERIOD

Edible tissues of chickens and turkeys: 3 days.

11. SPECIAL STORAGE PRECAUTIONS

Store between 15 and 25°C. Protect from light. Close container securely after use.
Keep out of the reach of children.
Shelf-life from date of manufacture: 2 years.
Shelf-life after first opening of container: 3 months.
Shelf-life after reconstitution in drinking water: 24 hours.

12. SPECIAL WARNING(S)

Special warnings for use in animals:
No special precautions are required.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Persons with known hypersensitivity to quinolones should avoid any contact with the product.
In order to avoid irritation of skin and/or eyes, use gloves and a face-protecting device when handling this product.
Pregnancy, lactation, lay:
Not applicable.

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

No additional precautions required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
1000 ml in plastic bottles with a screw cap
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.