# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT
DIFLOCIN 10% oral solution

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION
**Active substance**: Difloxacin (as hydrochloride) 100.0 mg
**Excipients**: Purified water
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
Treatment of respiratory, intestinal and systemic infections caused by difloxacin sensitive organisms in chickens and turkeys. 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 when eggs are intended for human use.

### 4.4. Special warnings for each target species
None.

### 4.5. Special precautions for use
Special precautions for use in animals
None.
Special safety precautions to be taken by person administering the 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)
None.

### 4.7. Use during pregnancy and lactation
Not applicable.

### 4.8. Interaction with other medicaments and other forms of interaction
No major undesirable interactions of difloxacin hydrochloride as the active substance of the drug product with other medicaments are known.

**4.9. Amounts to be administered and administration route**
To be administered orally, via the drinking water in such a concentration that ensures the daily intake of 10 mg difloxacin per kg of body weight. The administration must be continued for 3-5 days.
Taking into account the 10% content of difloxacin in the bottle, the following calculation should be made 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 the product may very rarely occurs because of good tolerance by the species to be used in. During the target animal tolerance studies, the product failed to induce any toxic effect even when administered at the threefold therapeutic dose 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 periods**
Meat and offal of chickens and turkeys: 1 day.

**5. PHARMACOLOGICAL PROPERTIES**
Pharmacotherapeutic group: quinolone antibiotics, ATCvet code: QJ01MA94
**Pharmacodynamic properties**
Difloxacin is a synthetic fluoroquinolone compound. It is bactericidal in action and acts by inhibition of bacterial DNA gyrase. Difloxacin is a broad-spectrum antimicrobial, being active against the most important gram-negative poultry pathogens (*E. coli*, *Salmonella spp.*, *Pasteurella spp*.) at minimum inhibitory concentrations $\leq 0.1$ μg/ml. The resistance rate of target bacteria against difloxacin is low (<10%).

**Pharmacokinetic particulars**
After oral administration, difloxacin is rapidly absorbed to reach steady-state plasma concentrations in 24 hours after initiation of medication. It is well distributed throughout the animal body providing higher concentrations in most tissues (among others, in the lungs) than in the plasma. Difloxacin concentrations equal to or greater than the MICs for the relevant pathogens are achieved in all relevant tissues and maintained for as long as treatment is continued.
*Chickens*
Data obtained from the plasma kinetic studies of Diflocin 10% Oral Solution in chickens indicate a high steady-state plasma concentration of difloxacin following the administration of the recommended dosage regimen. The average steady-state concentrations of 577 ng/ml are nearly 10-20 times higher than the MICs for the relevant pathogens.
*Turkeys*
In turkeys, the plasma levels of difloxacin was found to be about 4 times lower than those in chickens, with an average steady-state concentration of 141 ng/ml. The levels are, however, 2-4 times higher than the MICs for the relevant pathogens. Additionally, tissue to plasma ratios of difloxacin are known to be particularly high in turkeys, providing much higher drug concentration in the relevant tissues than in the plasma.

**6. PHARMACEUTICAL PARTICULARS**
**6.1. List of excipients**
Potassium hydroxide, propylene glycol, disodium edetate, benzyl alcohol, purified water.

**6.2. Incompatibilities**
None known.

**6.3. Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 3 months
Shelf-life after dilution according to directions: 24 hours

**6.4. Special precautions for storage**
Store between 15 and 25°C. Protect from frost. Close container securely after use.

**6.5. Nature and contents of container**
50 ml plastic bottles with a screw cap.
1000 ml plastic bottles with a screw cap.

**6.6 Special precautions for the disposal of unused, if any**
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**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.

**LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**
50 ml in plastic bottles with screw cap.
1000 ml in plastic bottles with screw cap.

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**
Diflocin 10% oral solution
Difloxacin (as hydrochloride)

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)**
Active substance: Difloxacin (as hydrochloride) 100.0 mg/ml

**3. PHARMACEUTICAL FORM**
Concentrate for oral solution.

**4. PACKAGE SIZE**
50 ml
1000 ml

**5. TARGET SPECIES**
Chickens and turkeys

**6. INDICATIONS**
Treatment of respiratory, intestined and systemic infections caused by difloxacin sensitive organisms in poultry, such as:

- 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*)

**7. METHOD AND ROUTE OF ADMINISTRATION**
For in-drinking water use.
Average dose: 10.0 mg difloxacin per kg of body weight daily.
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**
Meat and offal of chickens and turkeys: 1 day.

**9. SPECIAL WARNINGS**
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}
After first opening of container: 3 months
After reconstitution in drinking water: 24 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store between 15 and 25°C. Protect from frost.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of 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 REACH AND SIGHT OF CHILDREN"**

Keep out of reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER**

**17. MANUFACTURE'S BATCH NUMBER**

Batch: [number]

**PACKAGE LEAFLET FOR**
**Diflocin 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. 4/B, Hungary

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diflocin 10% oral solution
Difloxacin (as hydrochloride)

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

**Active substance:** Difloxacin (as hydrochloride) 100.0 mg/ml

## 4. INDICATIONS

Treatment of respiratory, intestinal and systemic infections caused by difloxacin sensitive organisms in poultry, such as:

- 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*)

## 5. CONTRAINDICATIONS

Do not use in laying hens when eggs are intended for human use.

## 6. ADVERSE REACTIONS

None.

## 7. TARGET SPECIES

Chickens and turkeys.

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

Dosage: 10.0 mg difloxacin per kg of body weight daily, administered in the drinking water for 3-5 days.

## 9. ADVICE on CIRRECT ADMINISTRATION

Taking into account the 10% content of difloxacin in the bottle, the following calculation should be made to determine the quantity in ml to be added per 1000 litres of water:

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

Medicated water should be refreshed every 24 hours.
No other of drinking water should be available during the medication period.

## 10. WITHDRAWAL PERIOD

Meat and offal of chickens and turkeys: 1 day.

**11. SPECIAL STORAGE CONDITIONS**
Store between 15 and 25°C. Protect from frost.

**12. SPECIAL WARNING(S)**
Special precautions for use in animals:
During the target animal tolerance studies, no adverse effect was observed even at the threefold therapeutic dose administered for two times the recommended duration.
If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.
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.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**15. DATE ON WHICH THE PACKAGE INSERT WAS LAST APPROVED**

**16. OTHER INFORMATION**
Pack sizes:
50 ml in plastic bottles with screw cap.
1000 ml in plastic bottles with 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.