

## **ENROTRON FLAVOUR 150 mg**

### **Tablets for dogs**

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

Marketing authorisation holder and manufacturer responsible for batch release:  
aniMedica GmbH  
Im Südfeld 9  
48308 Senden  
Germany

#### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Enrotron Flavour 150 mg Tablets for dogs  
Enrofloxacin

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

Each tablet contains: Active substance: Enrofloxacin, 150.0 mg.  
White to off-white, round tablet with one breakline and one decorative line. The tablet can be divided into two equal parts.

#### **4. INDICATIONS**

For the treatment of bacterial single or combined infections of the respiratory, alimentary or urinary tract, the skin or wounds, caused by Enrofloxacin-sensitive gram-negative and gram –positive bacteria: *E. coli*, *Pasteurella* spp., *Haemophilus* spp. and staphylococci.

#### **5. CONTRAINDICATIONS**

Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed)) as the product may cause epiphyseal cartilage alterations in growing puppies. Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation. Do not use in dogs with known hypersensitivity to fluoroquinolones or to any of the excipients of the product. Do not use in case of resistance to quinolones, as there exists almost complete cross resistance to other quinolones and complete cross resistance to other fluoroquinolones. Do not use with tetracyclines, phenicols or macrolides because of potential antagonistic effects. See also section 12. "Special Warnings".

#### **6. ADVERSE REACTIONS**

In rare cases vomiting and diarrhoea are observed.  
See section 5. "Contraindications".

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)



- very rare (less than 1 animal in 10,000 animals, including isolated reports)

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

## 7. TARGET SPECIES

Dogs.

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

Tablet for oral use.

Dose: 5 mg enrofloxacin per kg body weight (BW) daily, corresponding to: ½ tablet for 15 kg body weight; 1 tablet per 30 kg body weight.

Can be administered directly or given with food.

Treatment generally takes place over 5 - 10 consecutive days.

If there is no clinical improvement within 3 days, the sensitivity test is to be repeated and it may be necessary to switch to a different treatment.

The recommended doses should not be exceeded.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

## 9. ADVICE ON CORRECT ADMINISTRATION

None.

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

The expiry date refers to the last day of that month.

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

Divided tablets should be returned to the original package.

Shelf-life of divided tablets: 72 hours.

Do not store above 30°C.

## 12. SPECIAL WARNING(S)

**Special precautions for use in animals:** Official and local antimicrobial policies should be taken into account when the product is used. Skin infections are mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.

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 fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential cross resistance. As enrofloxacin is metabolized by the liver and partly eliminated via the kidneys, elimination may be delayed in dogs with liver or renal disturbances. Therefore, in cases of known liver or renal impairment, the product should be used with caution.

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals:** People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product. Wash hands after use.

In case of contact with the eyes, wash immediately with plenty of clean water.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

**Use during pregnancy, lactation or lay:** Pregnancy: Do not use during pregnancy; Lactation: Do not use during lactation.

**Interaction with other medicinal products and other forms of interaction:** Concurrent use of flunixin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.

Elimination of theophylline may be delayed.

Antagonistic effect may occur if enrofloxacin is combined with phenicols, macrolide antibiotics or tetracyclines.

Substances containing magnesium or aluminium, if administered at the same time, may impair the enrofloxacin resorption.

**Overdose (symptoms, emergency procedures, antidotes), if necessary:** Overdosing can cause vomiting and nervous signs (muscle tremor, incoordination and convulsions) which may require treatment discontinuation.

In the absence of any known antidote, apply drug elimination methods and symptomatic treatment.

If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.

According to literature, signs of overdose with enrofloxacin in dogs such as inappetence and gastrointestinal disturbance were observed at approximately 10 times the recommended dose when administered for two weeks. No signs of intolerance were observed in dogs administered 5 times the recommended dose for a month.

### **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.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

See SPC in your country.

### **15. OTHER INFORMATION**

10, 20, 30, 50, 100 tablets packed in blisters of 10 tablets consisting either of PVC / Aluminium foils or Aluminium / Aluminium foils

Cardboard box containing 1, 2, 3, 5, 10 blisters.

Not all pack sizes may be marketed.

For animal treatment only - to be supplied only on veterinary prescription.