PACKAGE LEAFLET:

Enrofloxacin WDT 150 mg Flavour 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:
To be completed nationaly.

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrofloxacin WDT 150 mg Flavour tablets for dogs
Enrofloxacin

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

Each tablet contains:

Active substance:

Enrofloxacin 150 mg

Excipients, q.s.

Round slightly biconvex, cream to light brownish tablets with possible visible white or darker spots, one side scored and bevel-edged. The tablet can be divided into equal parts.

4. INDICATION(S)

In dogs:

Treatment of infections caused by strains of *Staphylococcus* spp., *E. coli, Haemophilus* spp. *Pasteurella* spp., and *Salmonella* spp. susceptible to enrofloxacin.

The product is indicated for treatment of mono or mixed bacterial infections of the respiratory, digestive and urinary tract, otitis externa, skin and wound infections.

5. CONTRAINDICATIONS

Articular cartilage may be affected during the period of rapid growth, therefore do not use in dogs less than 1 year of age or in exceptionally large breeds of dog with a longer growth period less than 18 months of age.
Do not use in cases of hypersensitivity to the active substance, to any other quinolone or to any of the excipients.
Do not use in dogs having seizure disorders, since enrofloxacin may cause stimulation of the central nervous system.
Do not use in cases of known resistance to (fluoro)quinolones, as there exists almost complete cross resistance to other quinolones and complete cross resistance to other fluoroquinolones.
Please, see section 12 regarding use in pregnant and lactating animals.

6. ADVERSE REACTIONS

Occasionally gastrointestinal disturbances may occur. Hypersensitivity reactions and CNS disturbances may be observed.
Possible joint cartilage alterations in growing puppies (see 5. Contraindications).

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.
Alternatively you can report via your national reporting system
{national system details}

7. TARGET SPECIES

Dogs.

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

For oral use.
The dosage rate of enrofloxacin is 5 mg/kg/day (i.e. one 150 mg tablet per 30 kg per day), for 5 days. In chronic and severe cases, treatment duration can be extended to 10 days.

9. ADVICE ON CORRECT ADMINISTRATION

Tablets may be given directly into the mouth or masked in food.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
Treatment should be re-evaluated if no improvement is seen. It is commonly advised to re-evaluate the treatment if no clinical improvement is observed within 3 days.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Return any halved tablet to the opened strip-pack and use within 24 hours.
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.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Flouroquinolones should be reserved for the treatment of clinical conditions that 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. Official and local antimicrobial policies should be taken into account when the product is used. 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.
If there is no clinical improvement within three days, further susceptibility testing and possibly a change in antimicrobial therapy should be considered.
Use the product with caution in dogs with severe renal or hepatic impairment.
Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.
The product is flavoured. To avoid accidental ingestion, the tablets should be stored out of reach of 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.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with the eyes. In case of contact with the eyes, wash immediately with water.
Wash hands after use.
Do not smoke, eat or drink while handling the product.

Use during pregnancy, lactation or lay:
Do not use in pregnant or lactating bitches.

Interaction with other medicinal products and other forms of interaction:
Do not combine with other drugs, such as tetracyclines, phenicols or macrolides because there is a potential that these drugs nullify the desired effect.

Do not combine with theophylline (a drug used in medicine as a bronchial dilator) as this could lead to a prolonged elimination of this substance.
Do not use simultaneously with NSAIDs (convulsions may occur).
Concurrent use of flunixin and enrofloxacin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.
Concurrent administration of magnesium, calcium or aluminum containing substances may be followed by retarded absorption of enrofloxacin.
Excessive alkalinisation of the urine should be avoided in animals subjected to rehydration.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
In case of overdose, sickness, vomiting, diarrhoea, and CNS/behavioural changes may occur and the treatment must be suspended.
Do not exceed recommended dose.

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.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes:
Cardboard carton with 10 blister packs (100 tablets)
Cardboard carton with 1 blister pack (10 tablets)

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.