PACKAGE LEAFLET FOR:

Enrocill 50 mg/ml solution for injection for calves, pigs and 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:
Hifarmax, Lda, Av. Marechal Craveiro Lopes nº96 R/C Dto 2775-696 Carcavelos, Portugal

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocill 50 mg/ml solution for injection for calves, pigs and dogs
Enrofloxacin

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

Each ml contains:
Active substance:
Enrofloxacin 50 mg

Excipients:
n-butyl alcohol as antimicrobial preservative 30 mg

4. INDICATIONS

Treatment of infections caused by gram-positive bacteria, gram-negative bacteria and mycoplasmas susceptible to enrofloxacin in calves, pigs and dogs:

Calves: *E. coli*, *Haemophilus* spp., *Pasteurella* spp. *Mycoplasma bovis*.
Pigs: *E. coli, Actinobacillus pleuropneumoniae, Pasteurella multocida*.
Dog: *E. coli, Salmonella* spp., *Pasteurella* spp., *Haemophilus* spp., *Staphylococcus* spp.

Calves: Treatment of respiratory and alimentary tract diseases of bacterial or mycoplasmal origin (pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia), Postpartum Dysgalactiae Syndrome (PDS), pleuoropneumonia (caused by *Actinobacillus pleuropneumoniae*) and diseases of the respiratory tract (such as those caused by *Pasteurella multocida* and enzootic pneumonia).

Pigs: Treatment of respiratory and alimentary tract diseases of bacterial origin (pasteurellosis, coli-bacillosis, coli-septicaemia) and multifactorial diseases such as enzootic pneumonia.

Dogs: Treatment of mono or mixed bacterial infections of the respiratory, digestive and urinary tract, skin and wound infections.

5. CONTRAINDICATION

Do not use in case of disturbances in growth of cartilages and/or during injury of locomotory system.
Do not use in dogs less than 1 year of age or in exceptionally large breeds with a longer growth period under 18 months of age.

Do not use in dogs with CNS disturbances.
Do not use in bitches during pregnancy and lactation.
Do not use in case of hypersensitivity to the active substance.

6. ADVERSE REACTIONS

Local tissue reactions may occasionally occur at the injection site and may persist for 14 days.
In calves and dogs, gastrointestinal disturbances may occasionally occur.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (calves), pigs and dogs

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Calves: 2.5 mg enrofloxacin per kg bodyweight (1 ml per 20 kg bodyweight) daily by subcutaneous injection for 5 days.

Pigs: 2.5 mg enrofloxacin per kg bodyweight (1 ml per 20 kg bodyweight) daily by intramuscular injection for 3 days (1-2 days for treatment of PDS in sows). Injection should preferably be given in the neck musculature.

Dogs: 5 mg enrofloxacin per kg bodyweight (1 ml per 10 kg bodyweight) daily by subcutaneous injection for 5 days. For complicated and chronic diseases, the treatment period may be prolonged for up to 10 days.

If there is no clinical improvement within two to three days, further susceptibility testing and possibly a change in antimicrobial therapy should be considered.

9. ADVICE ON CORRECT ADMINISTRATION

The cap may be safely punctured up to 25 times. When treating groups of animals, use a draw-off needle.
Calves: Not more than 10 ml should be administered at one subcutaneous injection site.
Pigs: Not more than 2.5 ml should be administered at one intramuscular injection site.

10. WITHDRAWAL PERIOD

Calves: Meat and offal: 7 days
Pigs: Meat and offal: 7 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the immediate packaging: 28 days.
When the container is broached for the first time, using the in-use shelf life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.
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.
It is prudent to reserve enrofloxacin for the treatment of clinical conditions which have responded poorly to other classes of antimicrobials.
Use of the 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 potential for cross resistance.
Laboratory studies in laboratory animals have not produced any evidence of reproductive toxicity or teratogenic effects.
The safety of the veterinary medicinal product has not been established on pregnant sows. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.
Do not use in bitches during pregnancy or lactation.
When combined with macrolide antibiotics, tetracyclines and chloramphenicol (dog) enrofloxacin may produce an antagonistic effect.
Interactions may occur with drugs metabolised and eliminated by the liver. Theophylline clearance may be reduced in concurrent therapy with enrofloxacin.
In case of overdose symptoms consist of a weak spontaneous motility stimulation leading to discontinuation of treatment.

User Warnings
People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.
Do not eat, drink or smoke whilst using the 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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Vial of 50 and 100 ml.
Not all pack sizes may be marketed.