1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Enrofloxacin 50 mg

Excipients:
n-butyl alcohol 30 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear yellow solution practically free from particles

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calves), pigs, dogs

4.2 Indications for use, specifying the target species

Calves:
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*.

Pigs:
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*

Dogs:
Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of *Staphylococcus* spp., *Escherichia coli*, *Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

4.3 Contraindications

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 cases of hypersensitivity to the active substance, to any other quinolone or to any of excipients.
Do not use in growing horses because of possible deleterious damage on articular cartilage.
Do not use in case of resistance against other fluoroquinolones due to the potential for cross-resistance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

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.
Do not eat, drink or smoke whilst using the product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Local tissue reactions may very rarely occur at the injection site and may persist for 14 days.
In calves and dogs, gastrointestinal disturbances may very rarely occur.

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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

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.
Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

4.9 Amounts to be administered and administration route

Intravenous, subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.
To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.

Calves:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.
The product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at one subcutaneous injection.

Pigs:
2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/10 kg bw, once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by Escherichia coli: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.
In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

Dogs:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the SPC of the tablet product.

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

The cap may be safely punctured up to 25 times. When treating groups of animals, use a draw-off needle.

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

In case of overdose symptoms consist of a weak spontaneous motility stimulation leading to discontinuation of treatment.
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.
The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.

4.11 Withdrawal period(s)

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 13 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use. Fluoroquinolones.
ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

Enrofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase and topoisomerase IV, two enzymes essential in DNA replication and transcription. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.
Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli*, *Klebsiella* spp., *Actinobacillus pleuropneumoniae*, *Mannheimia haemolytica*, *Pasteurella multocida*, *Bordetella* spp., *Proteus* spp., *Pseudomonas* spp., against Gram-positive bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against *Mycoplasma* spp. at the recommended therapeutic doses.
Enrofloxacin reference breakpoints are available for *Mannheimia haemolytica* and *Pasteurella multocida* isolated from cattle (≥ 2 µg/ml, CLSI document M31-A3) and for *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* isolated from pigs (≥ 1 µg/ml, CLSI document M31-A4).

Several Susceptibility pan-European surveillances to investigate the susceptibility to enrofloxacin of bacterial strains isolated several pathologies in target species have been conducted. See main results below.

Susceptibility of bovine and porcine respiratory pathogens

Bacteria	Resistant (%)	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)
P. multocida – cattle	3	0.015	0.03
P. multocida – pigs	0	0.008	0.03
M. haemolytica – cattle	0.7	0.03	0.25
A. pleuropneumoniae	1.3	0.03	0.06

– pigs			

Broth microdilution method (El Garch et al., 2015)

Susceptibility of bovine and porcine mycoplasmas

	Resistant (%)	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)
M. bovis	NA	0.25	4
M. hyopneumoniae	NA	0.031	0.5

NA: No breakpoints were available (Klein et al., 2017)

Canine pathogens susceptibility (Com Path survey)

Respiratory pathogens

Bacteria	Resistant (%)	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)
S. intermedius – dogs	4.1	0.12	0.5
E. colli – dogs	12.5	0.06	>8
P. multocida – dogs	NA	0.015	0.015

NA: No breakpoints were available; agar dilution methodology (Morrisey et al., 2016):

Urinary tract pathogens

Bacteria	Resistant (%)	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)
E. colli – dogs	3.9	0.03	0.06
S. intermedius – dogs	3.0	0.12	0.25

(Moyaert et al., 2017)

Skin infections pathogens,

Bacteria	Resistant (%)	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)
S. pseudointermedius – dogs	5.2	0.12	0.5
S. aureus – dogs	2.2	0.12	0.25
E. coli – dogs	3.7	0.06	0.12
Pasteurella spp. – dogs	NA	0.015	0.015

NA: No breakpoints were available (Ludwig et al., 2016)

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

5.2 Pharmacokinetic particulars

Enrofloxacin has relatively high bioavailability after i.m. and s.c. administration in almost all of the species studied.
Following administration, the maximum plasma concentration of enrofloxacin is reached approximately 1-2 hours depending on the species, and antibacterial activity is still maintained after 24 hours.
Fluoroquinolones are characterized by extensive distribution to body fluids and tissues, reaching in some concentrations higher than those found in plasma. Fluoroquinolones are widely distributed in skin, bone and semen as well as in the anterior and posterior chambers of the eye; they cross the placenta and brain barrier. High levels are found in phagocytic cells (alveolar macrophages, neutrophils); therefore fluoroquinolones are effective against intracellular microorganisms.

The degree of metabolism varies between species and is around 50-60%. Enrofloxacin is biotransformed in the liver, to an active metabolite ciprofloxacin. Metabolism occurs via hydroxylation and oxidation. Other reactions involved are N-dealkylation and glucuronic acid conjugation.
Excretion occurs via the bile and kidney, the latter being predominant. The renal excretion is by glomerular filtration and tubular excretion.
In pigs, the administration after i.m. 2.5 mg / kg, the elimination half-life was 12.1 h, the mean residual time was 17.2 h and the maximum concentration was 1.2 ug / ml.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

n-butyl alcohol
Potassium hydroxide
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 amber Type I vial of 50 or 100 ml with a grey bromobutyl rubber stopper and aluminium cap.
Cardboard box with 1 amber Type II vial of 50 or 100 ml with a grey bromobutyl rubber stopper and aluminium cap.

Package sizes:
Carboard box with 1 vial of 50 ml
Carboard box with 1 vial of 100 ml

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Hifarmax, Produtos e Serviços Veterinários, Lda
Rua do Fojo 136, Pavilhão B - Trajouce
2785-615 S. Domingos de Rana – Portugal

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.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of solution for injection contains:
Active substance:
Enrofloxacin 50 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle (calves), pigs and dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Calves: iv. or sc.
Pigs: im.
Dogs: sc.

8. WITHDRAWAL PERIOD(S)

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf-life after first opening the immediate packaging: 28 days
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

Dispose of waste material 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 THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Hifarmax, Produtos e Serviços Veterinários, Lda
Rua do Fojo 136, Pavilhão B - Trajouce
2785-615 S. Domingos de Rana – Portugal

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of solution for injection contains:
Active substance:
Enrofloxacin 50 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cattle (calves), pigs and dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Calves: iv. or sc.
Pigs: im.
Dogs: sc.

8. WITHDRAWAL PERIOD(S)

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf-life after first opening the immediate packaging: 28 days
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

Dispose of waste material 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 THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Hifarmax, Produtos e Serviços Veterinários, Lda
Rua do Fojo 136, Pavilhão B - Trajouce
2785-615 S. Domingos de Rana – Portugal

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of solution for injection contains 50 mg enrofloxacin

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Calves: iv. or sc.
Pigs: im.
Dogs: sc.

8. WITHDRAWAL PERIOD(S)

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 13 days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:
Shelf-life after first opening the immediate packaging: 28 days
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

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 THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Hifarmax, Produtos e Serviços Veterinários, Lda
Rua do Fojo 136, Pavilhão B - Trajouce
2785-615 S. Domingos de Rana – Portugal

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET:

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, Produtos e Serviços Veterinários, Lda
Rua do Fojo 136, Pavilhão B - Trajouce
2785-615 S. Domingos de Rana – 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 30 mg

Clear yellow solution practically free from particles

4. INDICATION(S)

Calves:
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*.

Pigs: Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Dogs: Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections, otitis (externa/media) caused by enrofloxacin susceptible strains of *Staphylococcus* spp., *Escherichia coli*, *Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

5. CONTRAINDICATIONS

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 cases of hypersensitivity to the active substance, to any other quinolone or to any of excipients.
Do not use in growing horses because of possible deleterious damage on articular cartilage.
Do not use in case of resistance against other fluoroquinolones due to the potential for cross-resistance.

6. ADVERSE REACTIONS

Local tissue reactions may very rarely occur at the injection site and may persist for 14 days.
In calves and dogs, gastrointestinal disturbances may very rarely occur.

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

7. TARGET SPECIES

Cattle (calves), pigs and dogs

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

Intravenous, subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.

Calves:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.
The product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at one subcutaneous injection.

Pigs:
2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/10 kg bw, once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by Escherichia coli: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.

Dogs:

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the SPC of the tablet product.

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

10. WITHDRAWAL PERIOD(S)

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 13 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 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.
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)

Special precautions for use in animals:
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.

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.
Do not eat, drink or smoke whilst using the product.
Wash hands after use.

Pregnancy and lactation:
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.

Interaction with other medicinal products and other forms of interaction:
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.
Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

Overdose (symptoms, emergency procedures, antidotes):
In case of overdose symptoms consist of a weak spontaneous motility stimulation leading to discontinuation of treatment.
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.
The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Package sizes:
Carboard box with 1 vial of 50 ml.
Carboard box with 1 vial of 100 ml.
Not all pack sizes may be marketed.