SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROGAL 50 mg/ml
solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of the product contains:
Active substance:
Enrofloxacinum 50 mg
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Transparent yellowish to yellow solution of characteristic odour.

4. CLINICAL PARTICULARS

4.1. Target species

Calves, pigs, and dogs.

4.2. Indications for use, specifying the target species

Calves:
Bovine respiratory disease associated with *Haemophilus somnus, Pasteurella multocida*
Pigs:
Enteritis: *E.coli*
Metritis-mastitis-agalactia syndrome (MMA) caused by *E. coli, Klebsiella spp., Staphylococcus spp.*
Dogs:
Infections of skin, gastrointestinal, respiratory and urinary tracts caused by *E.coli, Salmonella spp., Pasteurella spp., Staphylococcus intermedius*

4.3. Contraindications

Do not use in animals suffering from CNS and joint disorders.
For small and medium breeds of dogs do not use in animals below 2-8 months of age. For large and very large dogs, the product should not be used in animals under 12 and 18 months of age, respectively (or until the growth phase is finished).

4.4. Special warnings for each target species

None

4.5. Special precautions for use

Special precautions for use in animals
Official and local antimicrobial policies should be taken into account when the product is used.
Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classe 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 the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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

To the physician: Enrofloxacin is a fluoroquinolone antibiotic, similarly as ciprofloxacin used in human medicine. Poisoning with the substance is unlikely.

In case of overdose, immediate first aid followed by decontamination of the affected person. Treatment is symptomatic.

4.6. Adverse reactions (frequency and seriousness)

Joints disorders accompanied with decreased mobility can occur when the fluoroquinolones are used.

Gastrointestinal tract disorders can sporadically occur in dogs and calves.

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

4.7. Use during pregnancy and lactation

Do not use in pregnant and lactating animals.

4.8. Interaction with other medicinal products and other forms of interaction

Simultaneous administration of chloramphenicol, tetracyclines, macrolide antibiotics has an antagonistic effect. Do not use simultaneously with non-steroidal antiinflammatory drugs or with theophyline.

Simultaneous administration of magnesium, aluminium, calcium, iron, zinc and copper decreases the resorption and efficacy of enrofloxacin.

4.9. Amounts to be administered and administration route

Calves

2,5 mg enrofloxacin per kg bodyweight (1 ml of the product/20 kg bw), subcutaneously, for 5 days

In serious infections 7,5 mg enrofloxacin per kg bodyweight (3 ml of the product/20 kg bw), single dose.

Do not administer more than 5 ml at the one injection site.

Pigs

2,5 mg enrofloxacin per kg bodyweight (1 ml of the product / 20 kg bw), intramuscularly, for 3 days, MMA 1 – 2 days.

Do not administer more than 2,5 ml at the one injection site.

Dogs

5 mg enrofloxacin per kg bodyweight (0,1 ml of the product/kg bw), subcutaneously, for 5 days, in chronic disease within 10 days.

Do not administer more than 5 ml at the one injection site.

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

After administration of large dose to young animals in growth phase (especially dogs), joint lesions, degenerative changes of cartilages can appear.

4.11. Withdrawal periods
Meat and offal: pigs 10 days, calves 14 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutical group: „fluoroquinolones“
ATCvet code: QJ01MA90.

5.1. Pharmacodynamic properties
Enrofloxacin belongs to ATCvet group QJMA90 (fluoroquinolone antibiotics).
Enrofloxacin acts by the inhibition of bacterial enzyme DNA-gyrase (topoisomerase II) which is important for the maintenance of the DNA spatial arrangement.
The major target pathogens with MIC_{90} are following:

- in calves: *Pasteurella multocida* (MIC_{90}=0,03 µg/ml) and *Haemophilus somnus* (MIC_{90}=0,06 µg/ml);
- in pigs: *Klebsiella pneumoniae* (MIC_{90}=0,0,125 µg/ml), *Escherichia coli* (MIC_{90}=0,12 µg/ml), *Staphylococcus spp.* (MIC_{90}=0,19 µg/ml),
- in dogs: *Escherichia coli* (MIC_{90}=0,06 µg/ml), *Salmonella spp.* (MIC_{90}=0,12 µg/ml), *Pasteurella multocida* (MIC_{90}=0,03-0,06 µg/ml), *Staphylococcus intermedius* (MIC_{90}=0,25 µg/ml).

Presented MIC_{90} in indicated pathogens, data on time-kill kinetics, postantibiotic effect and PK/PD analysis indicate a good bactericide effect of enrofloxacin on targer pathogens.

5.2. Pharmacokinetic properties
Enrofloxacin is rapidly and well resorbed after intramuscular (pigs) and subcutaneous (calves and dogs) administration. It is well distributed into the target tissues: lung, jejunum wall, kidneys, exudate or skin, when it reaches the greater concentrations than in plasma.
In calves, after subcutaneous administration of 2,5 mg enrofloxacin/kg bw, the following pharmacokinetic parameters were determined: T_{max}=2,25 h., C_{max}=0,491 µg/ml and AUC=3,116 µg.h/ml. After a single subcutaneous administration of 7,5 mg enrofloxacin/kg bw to calves, the following plasma values were determined for enrofloxacin: C_{max}=0,83 µg/ml, T_{max}=5,8 h, $T_{1/2}$=6,4 h. and $AUC_{0\text{-}48h.}$=8,66 µg.h/ml.
In pigs the following mean values were determined after intramuscular administration of 2,5 mg enrofloxacin/kg bw: C_{max}=1,19 µg/ml, T_{max}=1,78 h and AUC=19,42 µg.h/ml. Bioavailability was 77,46%, MRT 17,74 h, $V_{d(ss)}$ 1,77 l/kg and Cl 0,10 l/h/kg.
After s.c. administration of 5 mg enrofloxacin/kg bw to dogs, T_{max}=1,696 h., C_{max}=1,265 µg/ml aand AUC=6,384 µg.h/ml.
Partial metabolisation is done in liver. Major metabolite (N-deethyled enrofloxacin) acts antimicrobially and together with enrofloxacin participates on the product antimicrobial activity.
Enrofloxacin and its major metabolite (ciprofloxacin) are eliminated via bile (70%) and urine (30%).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Propyleneglycol,
1,3-Butanediol,
Ethanol 96%,
Disodium edetate dihydrate,

Sodium hydroxide,
Water for injection

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 28 days.

6.4. Special precautions for storage
Store below 25°C.
Protect from light.

6.5. Nature and composition of immediate packaging
Immediate package: glass vial (type I) of 100 ml with bromobutyl rubber stopper and aluminium cap.
Outer package: paper box.
Package size: 100 ml.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
PHARMAGAL spol. s r.o., Murgašova 5, 949 01 Nitra, Slovak Republic
e-mail: pharmagal@seznam.cz
tel: +421/37/741 97 59, fax: +421/37/741 97 58

8. MARKETING AUTHORISATION NUMBERS

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
Slovak Republic: 28th March 2001

10. DATE OF REVISION OF THE TEXT
12 2007

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PAPER BOX 100 ml

1.NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROGAL 50 mg/ml
solution for injection

2.STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Enrofloxacinum 50,0 mg/ml

3.PHARMACEUTICAL FORM

Solution for injection

4.PACKAGE SIZE

100 ml

5.TARGET SPECIES

Calves, pigs and dogs.

6.INDICATION(S)

Calves:
Bovine respiratory disease associated with *Haemophilus somnus, Pasteurella multocida*
Pigs:
Enteritis: *E. coli*
Metritis-mastitis-agalactia syndrome (MMA) caused by *E. coli, Klebsiella spp., Staphylococcus spp.*
Dogs:
Infections of skin, gastrointestinal, respiratory and urinary tracts caused by *E. coli, Salmonella spp., Pasteurella multocida, Staphylococcus intermedius*

7.METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs intramuscularly, other animals subcutaneously.

8.WITHDRAWAL PERIOD

Meat and offal: pigs 10 days, cattle 14 days.

9.SPECIAL WARNING(S)

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.
To the physician: Enrofloxacin is a fluoroquinolone antibiotic, similarly as ciprofloxacin used in human medicine. Poisoning with the substance is unlikely.
In case of overdose, immediate first aid followed by decontamination of the affected person. Treatment is symptomatic.

10.EXPIRY DATE

EXP:

11.SPECIAL STORAGE CONDITIONS

Shelf-life after first opening of immediate package: 28 days.
Store below 25°C. Protect from light.

12.SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

For animal treatment only.
To be supplied only on veterinary prescription.

14.THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15.NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PHARMAGAL, s.r.o., Murgašova 5, 949 01 Nitra, Slovak Republic

16.MARKETING AUTHORISATION NUMBER(S)

17.MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE IMMEDITE PACKAGE

Label 100 ml

1.NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROGAL 50 mg/ml
solution for injection

2.STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Enrofloxacinum 50,0 mg/ml

3.PHARMACEUTICAL FORM

Solution for injection

4.PACKAGE SIZE

100 ml

5.TARGET SPECIES

Calves, pigs and dogs.

6.INDICATION(S)

Read the package leaflet before use.

7.METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs intramuscularly, other animals subcutaneously.

8.WITHDRAWAL PERIOD

Meat and offal: pigs 10 days, cattle 14 days.

9.SPECIAL WARNING(S)

Read the package leaflet before use.

10.EXPIRY DATE

EXP:

11.SPECIAL STORAGE CONDITIONS

Shelf-life after first opening of immediate package: 28 days.
Store below 25°C. Protect from light.

12.SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

For animal treatment only.
To be supplied only on veterinary prescription.

14.THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15.NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PHARMAGAL, s.r.o., Murgašova 5, 949 01 Nitra, Slovak Republic

16.MARKETING AUTHORISATION NUMBER(S)

17.MANUFACTURER'S BATCH NUMBER

Batch:

PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER:

PHARMAGAL spol.s r.o. Nitra, Murgašova 5, 949 01 Nitra, Slovak Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROGAL 50 mg/ml
solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance:
1 ml contains:
Enrofloxacinum 50,0 mg/ml
Excipients:
Propyleneglycol, Butanediol, Ethanol 96 %, Disodium edetate dihydrate, Water for injection

4. INDICATIONS

Calves:
Bovine respiratory disease associated with *Haemophilus somnus, Pasteurella multocida*
Pigs:
Enteritis: *E.coli*
Metritis-mastitis-agalactia syndrome (MMA) caused by *E. coli, Klebsiella spp., Staphylococcus spp.*
Dogs:
Infections of skin, gastrointestinal, respiratory and urinary tracts caused by *E.coli, Salmonella spp., Pasteurella spp., Staphylococcus intermedius*

5. CONTRAINDICATIONS

Do not use in animals suffering from CNS and joint disorders.
For small and medium breeds of dogs do not use in animals below 2-8 months of age. For large and very large dogs, the product should not be used in animals under 12 and 18 months of age, respectively (or until the growth phase is finished).

6. ADVERSE REACTIONS

Joints disorders accompanied with decreased mobility can occur when the fluoroquinolones are used.
Gastrointestinal tract disorders can sporadically occur in dogs and calves.
If you notice any serious effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Calves, pigs and dogs.

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

Calves
2,5 mg enrofloxacin per kg bodyweight (1 ml of the product/20 kg bw), subcutaneously, for 5 days
In serious infections 7,5 mg enrofloxacin per kg bodyweight (3 ml of the product/20 kg bw), subcutaneously, single dose.
Do not administer more than 5 ml at the one injection site.
Pigs
2,5 mg enrofloxacin per kg bodyweight (1 ml of the product / 20 kg bw), intramuscularly, for 3 days, MMA 1 – 2 days.
Do not administer more than 2,5 ml at the one injection site.
Dogs
5 mg enrofloxacin per kg bodyweight (0,1 ml of the product/kg bw), subcutaneously, for 5 days, in chronic disease within 10 days.
Do not administer more than 5 ml at the one injection site.

9. ADVICE ON CORRECT ADMINISTRATION

Official and local antimicrobial policies should be taken into account when the product is used.
Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classe 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 the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

10. WITHDRAWAL PERIOD

Meat and offal: pigs 10 days, calves 14 days.

11. SPECIAL STORAGE PRECAUTIONS

Do not use after the expiry date specified on label.
Shelf-life after first opening of immediate package: 28 days.
Store below 25°C.
Portect from light.
Keep out of the reach and sight of children.

12. SPECIAL WARNINGS

Special precautions for animals
For small and medium breeds of dogs do not use in animals below 2-8 months of age. For large and very large dogs, the product should not be used in animals under 12 and 18 months of age, respectively (or until the growth phase is finished).

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show tha package leaflet or label to the physician.
To the physician: Enrofloxacin is a fluoroquinolone antibiotic, similarly as ciprofloxacin used in human medicine. Poisoning with the substance is unlikely.
In case of overdose, immediate first aid followed by decontamination of the affected person. Treatment is symtomatic.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT FOR WASTE MATERIAL

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: 12 / 2007

15. OTHER INFORMATION

Interactions
Simultaneous administration of chloramphenicol, tetracyclines, macrolide antibiotics has an antagonistic effect. Do not use simultaneously with non-steroidal antiinflammatory drugs or with theophyline.
Simultaneous administration of magnesium, aluminium, calcium, iron, zinc and copper decreases the resorption and efficacy of enrofloxacin.

Package size: 100 ml
For animal treatment only.
To be supplied only on veterinary prescription.