LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of solution for injection contains:
Enrofloxacin 50 mg and Butyl alcohol 30 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle (calves)
Pigs weighing more than 25kg
Dogs and cats

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTES OF ADMINISTRATION

Calves	**Pigs (weighing more than 25kg)**	**Dogs and Cats**
5 mg enrofloxacin per kg bodyweight (1 ml/10 kg) daily by slow intravenous or subcutaneous injection for 3 to 5 days.	2.5 mg enrofloxacin per kg bodyweight (0.5 ml/10 kg) daily by intramuscular injection for 3 days.	5 mg enrofloxacin per kg bodyweight (1.0 ml/10 kg) daily by subcutaneous injection for up to 5 days.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Calves:
IV: Meat and offal: 5 days.
SC: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.

Pigs:

Meat and offal: 13 days.

9. SPECIAL WARNINGS, IF NECESSARY

User warnings:

This product is an alkaline solution. Wash any splashes from skin and eyes immediately with water.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.
Do not eat, drink or smoke whilst using the product.
In case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician.

The vial seal may be punctured up to a maximum of 25 times for the 100 ml vials, or 50 times for the 250ml vials.
Read the package leaflet before use.

10. EXPIRY DATE

EXP: DD/MM/YY
Once broached, use by:
Shelf-life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C
Do not freeze.
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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Animalcare Limited
10 Great North Way
York
YO26 6RB
UK

16. MARKETING AUTHORISATION NUMBER

UK: Vm 10347/4029

IE: VPA 10543/001/002

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN>

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL LABELS (100ml and 250ml vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Enrofloxacin 50 mg/ml
Butyl alcohol as antimicrobial preservative 30 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: sc, iv
Pigs weighing more than 25 kg: im.
Dogs: sc.
Cats: sc.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Calves:
IV: Meat and offal: 5 days.
SC: 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.
Do not use for prophylaxis. Do not use in dogs under 1 year of age, in exceptionally large breeds of dog with a longer growth period under 18 months of age, or cats less than 8 weeks of age. To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing. Do not exceed the recommended dose. Do not use in case of hypersensitivity to the active substance or to

any of the excipients. Local tissue reactions may occur at the injection site. Normal sterile precautions should be taken.

User warnings:

This product is an alkaline solution. Wash any splashes from skin and eyes immediately with water.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.
Do not eat, drink or smoke whilst using the product.
In case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician.

10. EXPIRY DATE

EXP: DD/MM/YY
Once broached, use by:
Shelf life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC
Do not freeze.
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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Animalcare Ltd
10 Great North Way
York
YO26 6RB
UK

16. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 10347/4029

IE: VPA 10543/001/002

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN>

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Enrocare 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats
Enrofloxacin

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

Marketing Authorisation Holder

Animalcare Ltd
10 Great North Way
York
YO26 6RB
UK

Manufacturer for the batch release
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonkveer
Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats (UK, IE, FR)
Floxadil 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats (NL, LU)
Enrofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml of solution for injection contains 50 mg of enrofloxacin and 30 mg of butyl alcohol as antimicrobial preservative.
Enrocare 50 mg/ml Solution for Injection is a clear, light yellow, sterile, aqueous solution.

4. INDICATIONS

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.

Cats
Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of, e.g.: *Staphylococcus* spp*., Escherichia coli, Pasteurella* spp*., Klebsiella* spp*., Bordetella* spp*., Pseudomonas* spp. and *Proteus* spp.

5. CONTRAINDICATIONS

Do not use in cases of resistance against other fluoroquinolones, due to the potential for cross-resistance.
Do not use in dogs under 1 year of age as damage to the articular cartilage may occur during the period of rapid growth, specifically in large breeds of dog. As a precaution very large breeds of dog should not be treated with the product until they are 18 months of age because of their longer growth period.
Do not use in cats less than 8 weeks of age.
Do not use in growing horses because of possible deleterious damage on articular cartilage.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Local tissue reactions may occur at the injection site.
Occasionally skin reactions have been seen after administration to kennelled greyhounds.
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 weighing more than 25 kg
Dogs and cats

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

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

Calves
5 mg of enrofloxacin/kg body weight (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 site.

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 and cats
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once 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.

The vial seal may be punctured up to a maximum of 25 times for the 100 ml vials, or 50 times for the 250ml vials.

9. ADVICE ON CORRECT ADMINISTRATION

Normal sterile precautions should be taken.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
When the container is broached (opened) 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.

10. WITHDRAWAL PERIODS

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.
Do not store above 25°C
Keep the vial in the outer carton in order to protect from light
Do not freeze.
Do not use after the expiry date stated on the label and carton after "EXP"
Shelf-life after first opening the immediate packaging: 28 days

12. SPECIAL WARNINGS

Special warnings for each target species

Cats
Retinotoxic effects including blindness can occur in the cat when the recommended dose is exceeded.

Special precautions for use in animals
Do not use for prophylaxis. Do not exceed the recommended dosage. Repeat injections should be made at different sites. Do not use in dogs and cats with CNS disturbances. 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.
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 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 the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

User warnings
This product is an alkaline solution. Wash any splashes from skin and eyes immediately with water.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.
Do not eat, drink or smoke whilst using the product.
In case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician.

Use during pregnancy, lactation or lay
There is no restriction on the use of this product during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction
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)
Do not exceed the recommended dosage. In accidental overdose there is no antidote and treatment should be symptomatic.

In target animal studies, cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

No target animal studies were performed in cattle. In pigs, no adverse effects were observed after administration of the product at 5 times the recommended therapeutic dose.

Incompatibilites
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused 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

December 2014

15. OTHER INFORMATION

Prescription only medicine
Vials of 100 ml or 250 ml. Not all pack sizes may be marketed.