A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 25 mg/ml Solution for Injection for Dogs, Cats, Rabbits, Rodents, Reptiles and Ornamental birds
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of solution for injection contains:
Enrofloxacin 25 mg and Butyl alcohol 30 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Dogs, cats ,rabbits, rodents, reptiles and ornamental birds

6. INDICATIONS

For the treatment of certain bacterial infections in dogs, cats, rabbits, rodents, reptiles and ornamental birds.

Read the package leaflet before use.

7. METHOD AND ROUTES OF ADMINISTRATION

Dogs and Cats	**Small mammals**	**Reptiles**	**Avian spp**
5 mg enrofloxacin per kg bodyweight (1 ml/5 kg) by subcutaneous injection once daily for up to 5 days.	10 mg enrofloxacin per kg bodyweight (0.4 ml /kg) by subcutaneous injection once daily for 5 to 10 days.	5-10 mg enrofloxacin per kg bodyweight (0.2-0.4 ml /kg) by intramuscular injection at 24-48 hour intervals for 5 days.	20 mg enrofloxacin per kg bodyweight (0.8 ml /kg) by intramuscular injection, once daily for 5 to 10 days.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Rabbits:
Meat and offal: 6 days.

Do not use in birds intended for human consumption.

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.
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 container 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 10347/4028

IE: VPA 10543/001/001

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN>

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL (100ml Vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 25 mg/ml Solution for Injection for Dogs, Cats, Rabbits, Rodents, Reptiles and Ornamental birds.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Enrofloxacin 25 mg/ml
Butyl alcohol as antimicrobial preservative 30 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

6. INDICATION(S)

For the treatment of certain bacterial infections in dogs, cats, rabbits, rodents, reptiles and ornamental birds.
Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs and cats: sc.
Small mammals: sc
Reptiles: im
Birds: im

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Rabbits:
Meat and offal: 6 days.
Do not use in birds intended for human consumption.

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 container 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 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 10347/4028

IE: VPA 10543/001/001

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label (50ml Vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocare 25 mg/ml Solution for Injection for Dogs, Cats, Rabbits, Rodents, Reptiles and Ornamental birds
Enrofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE

1 ml of solution contains 25 mg enrofloxacin

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTES OF ADMINISTRATION

Dogs and cats: sc.
Small mammals: sc
Reptiles: im
Birds: im

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Rabbits:
Meat and offal: 6 days.
Do not use in birds intended for human consumption.

6. BATCH NUMBER

<Batch> <Lot> <BN>

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Enrocare 25 mg/ml Solution for Injection for Dogs, Cats, Rabbits, Rodents, Reptiles and Ornamental birds
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 25mg/ml Solution for Injection for Dogs, Cats, Rabbits, Rodents, Reptiles and Ornamental birds (UK, IE, FR)
Floxadil 25mg/ml Solution for Injection for Dogs, Cats, Rabbits, Rodents, Reptiles and Ornamental birds (NL, LU)
Enrofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml of solution for injection contains 25 mg of enrofloxacin and 30 mg of Butyl Alcohol as antimicrobial preservative.
Enrocare 25 mg/ml Solution for Injection is a clear, light yellow, sterile, aqueous solution.

4. INDICATIONS

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: *Staphylococcus* spp*., Escherichia coli, Pasteurella* spp*., Klebsiella* spp*., Bordetella* spp*., Pseudomonas* spp. and *Proteus* spp.

Rabbits
Treatment of infections of the alimentary and respiratory tracts caused by enrofloxacin susceptible strains of: *Escherichia coli*, *Pasteurella multocida* and *Staphylococcus* spp.
Treatment of skin and wound infections caused by enrofloxacin susceptible strains of *Staphylococcus aureus*.

Rodents, reptiles and ornamental birds Treatment of infections of the alimentary and respiratory tracts where clinical experience, if possible, supported by susceptibility testing of the causal organism, indicates enrofloxacin as the substance of choice.

5. CONTRAINDICATIONS

Do not use in cases of resistance against other fluoroquinolones, due to the potential for cross-resistance.
Do not use in dogs less than one year of age or in exceptionally large breeds of dog with a longer growth period under 18 months of age.
Do not use in cats less than 8 weeks of age.
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

Dogs, cats, rabbits, rodents, reptiles and ornamental birds

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

Subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.

Dogs and cats
5 mg of enrofloxacin/kg body weight (bw), corresponding to 1 ml/5 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 product information of the tablet product.

Rabbits
10 mg/kg bw, corresponding to 2 ml/5 kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days.

Rodents
10 mg/kg bw, corresponding to 0.4 ml/kg bw, once daily by subcutaneous injection for 5 to 10 consecutive days. If necessary, depending on the severity of clinical signs, this dosage can be doubled.

Reptiles
Reptiles are ectothermic, relying on external heat sources to maintain their body temperature at the optimum level for correct function of all body systems. Metabolism of substances and activity of the immune system are, thus, critically dependent on the body temperature. Therefore, the veterinarian must be aware of the correct temperature requirements of the respective reptile species and the hydration status of the individual patient. Furthermore, it has to be considered that large differences exist in the pharmacokinetic behaviour of enrofloxacin among different species, which additionally will influence the decision about the correct dosage of Enrocare 25mg/ml. Therefore, the recommendations made here can only be used as a starting point for individual dose setting.
5–10 mg/kg bw, corresponding to 0.2–0.4 ml/kg bw, once daily by intramuscular injection for 5 consecutive days.

An extension of the treatment interval to 48 hours may be necessary in individual cases. In complicated infections, higher dosages and longer treatment courses may be necessary. The presence of the renal portal system in reptiles means it is prudent to administer substances in the front half of the body wherever possible.

Ornamental birds
20 mg/kg bw, corresponding to 0.8 ml/kg bw, once daily by intramuscular injection for 5 to 10 consecutive days. In case of complicated infections higher doses may be necessary.

The vial seal may be punctured up to a maximum of 25 times.

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

Rabbits:
Meat and offal: 6 days.

Do not use in birds intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight andreach of children.
Do not store above 25°C
Do not freeze.
Keep the vial in the outer carton in order to protect from light
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.

Reptiles and ornamental birds
Muscle bruising after injection in reptiles and birds has been reported occasionally.

Special precautions for use in animals
Official and local antimicrobial policies should be taken into account when the product is used.
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.

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 of the bitch or queen. In the absence of data on its use in some exotic species, caution should be used when prescribing during these periods and a careful risk/benefit assessment made.

Interaction 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 dose. 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.

Incompatibilites
None known

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2014

15. OTHER INFORMATION

Prescription only medicine
Vials of 50 ml or 100 ml. Not all pack sizes may be marketed.