IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

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

PRODUCT SUMMARY

EU Procedure Number	IE/V/0455/001 (formerly UK/V/0334/001)
Name, Strength, Pharmaceutical Form	Enrocare 25 mg/ml Solution for Injection for Dogs, Cats, Rabbits, Rodents, Reptiles and Ornamental birds
Active Substances(s)	Enrofloxacin
Applicant	Emdoka bvba John Lijsenstraat 16 B-2322 Hoogstraten Belgium
Legal Basis of Application	Generic application (Article 13(1) of Directive No 2001/82/EC)
Target Species	Cats, Dogs, Gerbils, Hamsters, Other Birds, Rabbits, Reptiles
Indication For Use	Dogs and cats: For the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice. Exotic animals (small mammals, reptiles and avian species): For the treatment of bacterial infections of the alimentary and respiratory tracts where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.
ATC Code	QJ01MA90
Date of completion of the original decentralised procedure	22 December 2009 (UK) 20May 2010 (IE)
Concerned Member States for original procedure	France Ireland (now RMS) Luxembourg Netherlands UK added via change of RMS

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.
The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

Enrocare 25 mg/ml solution for injection for dogs, cats and exotic animals contains the active substance enrofloxacin. The product is authorised to be used in dogs, cats and exotic animals. In dogs and cats, the product is used in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice. In exotic animals, the product is used for the treatment of bacterial infections of the alimentary and respiratory tracts where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

This application is a generic made in accordance with Article 13(1) of Directive 2001/82/EC. The reference product is Baytril 2.5% solution for injection which has been marketed in the UK since 1992.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species and the slight reactions observed are indicated in the SPC. The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy of the product was demonstrated according to the claims made in the SPC.

II. QUALITY ASPECTS

A. Composition
The product contains enrofloxacin as an active substance and butyl alcohol, potassium hydroxide and water for injections as excipients.
The product is packaged in an amber Type 1 multidose glass vial with a grey bromobutyl rubber stopper and aluminium overseal.
The particulars of the containers and controls performed are provided and conform to the regulation.
The choice of the formulation is justified.

B. Method of Preparation of the Product
The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.
Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials
The active substance enrofloxacin is an established active substance and supporting data have been provided in the form of European Drug Master File (EDMF). It is considered that the manufacturing process is adequately controlled and the active substance specification has been suitably justified.

There are three excipients used in the formulation and each has been used previously in veterinary medicines. Potassium hydroxide and water for injections have monographs in the Ph. Eur. and each complies with the requirements of the current edition of the Ph. Eur. In the absence of a monograph in the European Pharmacopoeia, the requirements of the monograph in the United States Pharmacopoeia National Formulary are applied in the raw material specification for butyl alcohol.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies
A declaration from the applicant has been provided which states that Enrocare 25 mg/ml solution for injection for dogs, cats and exotic animals complies with the latest version of the CPMP/CVMP guidelines on TSEs. Additional declarations have also been provided by the manufacturers of the active substance and suppliers of the excipients confirming that no materials of animal origin are used during their manufacture.

E. Control on intermediate products
There are no intermediate products.

F. Control Tests on the Finished Product
The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.
Satisfactory validation data for the analytical methods have been provided.

G. Stability
Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life. The shelf-life of the veterinary medicinal product as packaged for sale is 3 years. An in-use shelf life of 28 days is justified.

H. Genetically Modified Organisms
Not applicable

J. Other Information
Special Precautions for Storage:

Do not store above 25°C
Do not freeze.
Keep the vial in the outer carton in order to protect from light.
Discard unused material.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, data on pharmacodynamics and pharmacokinetics are not required.

Toxicological Studies

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, data on toxicology are not required.

Other Studies

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, the applicant has not submitted any data for this section.

User Safety

The following operator warnings are included in the SPC and product literature:

> 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.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline. In accordance with the Phase I decision tree, the treatment of dogs and cats does not result in extensive exposure of the environment. The small mammals, birds, reptiles and exotic animals are non-food animals, and are not considered as major species, environmental exposure will be low. Therefore, the assessment can end at Phase I. The warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT

Pharmacology

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, data on pharmacodynamics and pharmacokinetics are not required.

Tolerance in the Target Species of Animals

As the product has the same pharmaceutical form and the same qualitative and quantitative composition as the reference product, no new target species tolerance data have been presented. This complies with exemptions specified under Article 13 (2)(b) of Directive 2001/82/EC as amended by 2004/28/EC.

Resistance

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. 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 cross-resistance.
Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, data on clinical efficacy are not required.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.