

IPAR



Publicly Available Assessment Report for a **Veterinary Medicinal Product**

Enrox 100 mg/ml oral solution

PRODUCT SUMMARY

EU Procedure number	IE/V/0181/001/MR
Name, strength and pharmaceutical form	Enrox Oral solution 100 mg/ml
Active substance(s)	Enrofloxacin
Applicant	Krka, d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto, Slovenia
Legal basis of application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended
Date of Authorisation	9 th September 2005
Target species	Chickens and turkeys
Indication for use	Treatment of infections caused by the following bacteria susceptible to enrofloxacin: Chickens <i>Mycoplasma gallisepticum</i> , <i>Mycoplasma synoviae</i> , <i>Avibacterium paragallinarum</i> , <i>Pasteurella multocida</i> , <i>Escherichia coli</i> . Turkeys <i>Mycoplasma gallisepticum</i> , <i>Mycoplasma synoviae</i> , <i>Pasteurella multocida</i> , <i>Escherichia coli</i> .
ATCvet code	QJ01MA90
Concerned Member States	AT, EL, IT, NL, SI

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

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; 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.
The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains the active substance enrofloxacin (100 mg/ml) and the excipients benzyl alcohol, hydroxypropylmethylcellulose, potassium hydroxide, and purified water.

The product is packaged in glass vials of 100 ml and in polyethylene bottles of 1 L and 5 L. The 100 ml and 1 L presentations are supplied with a measuring cup.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is enrofloxacin, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on Intermediate Products

Not applicable.

E. 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 has been provided.

Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product has been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, on the basis of essential similarity to the reference product Baytril 10% Oral Solution (Bayer). Given the legal basis of the application, no pharmacological or toxicological studies have been presented.

Exemption from bioequivalence studies (in accordance with paragraph 4(e) of the Guideline for Conduct of Bioequivalence Studies (EMA/CVMP/016)) is accepted because the product is an oral solution containing an active substance in the same concentration as a product approved for use in the same target species, and it contains no inactive substance that can significantly affect the absorption of the active substance.

As the product is accepted as being bioequivalent to Baytril 10% Oral Solution, the safety profile is assumed to be the same.

Warnings and precautions as listed on the product literature reflect those of the reference product. These are considered adequate to ensure safety to the target animal, the user and the environment when the product is used as directed.

III.B Residues Documentation

Residue Studies

No residue depletion studies were conducted for reasons stated in section III.A. No data for MRLs were presented since Enrofloxacin is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010.

The withdrawal period as published in accordance with the Commission Decision regarding the Article 35 referral on products containing enrofloxacin to be administered via drinking water to chickens and/or turkeys will apply (7 days for chickens and 13 days for turkeys). The product is not authorised for use in laying birds producing eggs for human consumption and is not to be administered to layer replacement birds within 14 days of coming into lay.

IV CLINICAL ASSESSMENT (EFFICACY)

No clinical data were presented for the reasons stated in section III.A. The indications, target animal warnings, dosage and administration are equivalent to those of the reference product.

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.

VI POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Safety/Efficacy Changes

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Summary of change (7017574)	Approval date
Update of the SPC following the publication of an Article 35 referral on products containing enrofloxacin to be administered via drinking water to chickens and/or turkeys. (IE/V/0181/001/IA/006)	17/04/2014