

IPAR



Publicly Available Assessment Report for a Veterinary Medicinal Product

Spectron 100 mg/ml solution for use in drinking water for chickens and turkeys

PRODUCT SUMMARY

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| EU Procedure number | IE/V/0248/001/DC |
| Name, strength and pharmaceutical form | Spectron 100 mg/ml solution for use in drinking water for chickens and turkeys |
| Active substance | Enrofloxacin |
| Applicant | LABORATORIOS HIPRA, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain |
| Legal basis of application | Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended. |
| Date of completion of procedure | 29 th September 2010 |
| Target species | Chicken and Turkey |
| Indication for use | For the treatment of diseases of the respiratory and alimentary tracts of bacterial or mycoplasmal origin (e.g. pasteurellosis, mycoplasmosis, colibacillosis and salmonellosis), where clinical experience supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice. |
| ATCvet code | QJ01MA90 |
| Concerned Member States | BE, CZ, DE, EL, FR, HU, IT, LT, LV, PT, SK, UK |

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 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 Enrofloxacin 100 mg/ml and the excipients butyl alcohol, potassium hydroxide and purified water. The container/closure system consists of 1 litre and 5 litre HDPE containers with HDPE screw cap.

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 described in the European Pharmacopoeia. 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 have 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 have been provided.

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

F. Stability

Stability data on the active substance have 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 have 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 (a generic application).

Exemption from bioequivalence studies (in accordance with paragraph 4(e) of the Guideline for Conduct of Bioequivalence Studies (EMEA/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 (Baytril 10% Oral Solution), and it contains no inactive substance that can significantly affect the absorption of the active substance.

As the test product is bioequivalent to Baytril 10% Oral Solution, it is accepted that the safety profile (safety to the target species and safety to the user) will be similar to that of the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

An environmental risk assessment in accordance with relevant guidance was presented in support of this application. The assessment concluded that the product when used as recommended will not pose a risk to the environment. No warnings are therefore required.

III.B Residues Documentation

Residue Studies

No residue depletion studies were provided.

MRLs

Enrofloxacin is listed in Table 1 of the Annex of Commission Regulation (EU) No. 37/2010 (O.J 20.1.2010, L15/30). The marker substance is the sum of enrofloxacin and ciprofloxacin.

MRLs are listed below:

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|------------|---|
| | Poultry |
| Muscle | 100 µg/kg |
| Liver | 200 µg/kg |
| Kidney | 300 µg/kg |
| Fat / skin | 100 µg/kg |
| Eggs | Not for use in animals from which eggs are produced for human consumption |

Withdrawal Periods

Given that the test and reference products can be considered bioequivalent, it is accepted that there will be no difference between products with respect to depletion of residues. Therefore, the proposed withdrawal period for the test product for both chickens and turkeys is the same as that authorised for the reference product in Ireland (that is, 3 days) and can be accepted.

IV CLINICAL ASSESSMENT (EFFICACY)

The application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended (a generic application).

Exemption from bioequivalence studies (in accordance with paragraph 4(e) of the Guideline for Conduct of Bioequivalence Studies (EMEA/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 (Baytril 10% Oral Solution), and it contains no inactive substance that can significantly affect the absorption of the active substance.

As the test product is bioequivalent to Baytril 10% Oral Solution, it is accepted that the efficacy profile will be similar to that of the reference product. The claimed indication and proposed posology are in line with that of the authorised reference product in Ireland.

A target animal safety study specific to the test product has not been presented with the application. Given that:

- The product is an oral dose form,
- Bioequivalence with the reference product Baytril 10% Oral Solution is accepted
- The toxicological profile of the active substance is well known
- The impurity profile in the formulation is satisfactory
- The excipients are recognised as being safe

the absence of tolerance studies specific to the test product can be accepted. It is accepted that the target animal safety profile of the test product will be the same as that 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.

Changes:

None.