# IPAR

# Publicly Available Assessment Report for a Veterinary Medicinal Product

Trioxyl 500 mg/g powder for use in drinking water for chickens, turkeys, ducks and pigs

## PRODUCT SUMMARY

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|---|---|
| Name, strength and pharmaceutical form | Trioxyl 500 mg/g powder for use in drinking water for chickens, turkeys, ducks and pigs |
| Active substance | Amoxicillin trihydrate |
| Applicant | Univet Ltd.,<br>Tullyvin,<br>Cootehill,<br>Co. Cavan |
| Legal basis of application | Informed consent application in accordance with Article 13(c) of Directive 2001/82/EC as amended. |
| Date of Authorisation | 27th January 2017 |
| Target species | Chickens, turkeys, ducks and pigs |
| Indication for use | Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.<br>Pigs: For the treatment of pasteurellosis. |
| ATCvet code | QP54AA04 |

## 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 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 quality / safety / efficacy aspects of this product is/are identical to Citramox 500 mg/g powder for use in drinking water for chickens, turkeys, ducks and pigs (VPA 10786/005/001).

## II QUALITY ASPECTS

See section I.

## III SAFETY ASSESSMENT

See section I.

## IV CLINICAL ASSESSMENT (EFFICACY)

See section I.

## V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

## 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.