IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Tolfine

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Tolfine
Active substance(s)	Tolfenamic acid
Marketing Authorisation Holder	Vetoquinol Ireland Limited 12 Northbrook Road Ranelagh Dublin 6 Ireland
Target species	Cattle and Pigs
Indication for use	Tolfine is indicated: • in cattle, as an adjunct in the treatment of pneumonia by improving general conditions and nasal discharge and as an adjunct in the treatment of acute mastitis. • in pigs, as an adjunct in the treatment of Metritis Mastitis Agalactia syndrome.
ATCvet code	QM01AG02

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 website.

I. SCIENTIFIC OVERVIEW

The initial application for the product was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available. Please refer to Section VI for significant post-approval changes which are important for the quality, safety and efficacy of the product.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

III. SAFETY ASSESSMENT

See section I.

IV. CLINICAL ASSESSMENT

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.

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.

Quality Changes

Summary of change **(Application number)**	**Approval date**
Change in the name and/or address of the marketing authorisation holder (CRN7021600)	August 2015
Change in the finished product formulation; removal of the antioxidant sodium formaldehyde sulfoxylate (CRN0099XR)	April 2021