IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Soloxine 0.8 mg Tablet

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Soloxine 0.8 mg Tablet
Active substance(s)	Levothyroxine sodium
Marketing Authorisation Holder	Virbac S.A. Virbac 1 1ére Avenue – 2065 m – L.I.D. 06516 Carros Cedex France
Date of Authorisation	27th October 1993
Target species	Dogs
Indication for use	For the long term treatment of thyroid insufficiency in dogs
ATCvet code	QH03AA01

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 IMB 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 Soloxine Tablets 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.

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 Soloxine Tablets demonstrated adequate evidence of efficacy for the approved indication(s) 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.

None.