IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

SYNULOX Palatable Tablets 50 mg

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Synulox Palatable Tablets 50 mg
Active substance(s)	Amoxicillin trihydrate Potassium clavulanate
Applicant	Zoetis Belgium S.A. 2nd Floor, Building 10 Cherrywood Business Park Loughlinstown Co Dublin Ireland
Legal basis of application	Full application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of Authorisation of procedure	1st October 1997
Target species	Cats and dogs
Indication for use	Indication for the treatment of a wide range of diseases of cats and dogs including: Skin disease (including deep and superficial pyodermas); soft tissue infections (abscesses and anal sacculitis); dental infections (eg gingivitis); urinary tract infections; respiratory disease (involving upper and lower respiratory tract); enteritis.
ATCvet code	QJ01CR02

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 initial application for Synulox Palatable Tablets 50 mg 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

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the IMB considered that Synulox Palatable Tablets 50 mg demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory risk/benefit 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.

Changes:

Safety/Efficacy Changes

Summary of change **(Application number)**	**Approval date**

C.1.3.a) variation to include additional safety warnings. CRN: 7008306	17th November 2010