IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Olab Sultrim 21% Premix for Medicated Feed

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Olab Sultrim 21% Premix for Medicated Feed
Active substance	Sulphadiazine Trimethoprim
Marketing Authorisation Holder	Oldcastle Laboratories Cogan Street Oldcastle County Meath
Legal basis of application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC as amended.
Date of Authorisation	24th April 1995
Target species	Pigs
Indication for use	For use in the treatment of diseases caused by bacteria sensitive to potentiated sulphonamide preparations.
ATCvet code	QJ01EW10

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 are identical to Sulfoprim 21% Premix for Medicated Feed (VPA 10990/025/001). The initial application for Sulfoprim 21% Premix for Medicated Feed was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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 (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.