IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Surolan Ear Drops and Cutaneous Suspension

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Surolan Ear Drops and Cutaneous Suspension
Active substances	Miconazole Nitrate Ph. Eur. Prednisolone Acetate Ph. Eur. Polymixin B Sulphate Ph. Eur.
Marketing Authorisation Holder	Elanco GmbH Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany
Date of Authorisation	1st October 1988
Target species	Cats and Dogs
Indication for use	For the topical treatment of otitis externa and skin infections caused by Gram-negative bacteria e.g. *Staphylococcus aureus*, *Streptococcus* spp., and Gram-negative bacteria *Escherichia coli andPseudomonas aeruginosa*. For the topical treatment of otitis externa and skin infections caused by fungi and yeasts: *Trichophyton* spp., *Microsporum* spp., *Malassezia pachydermatis, Candida* spp. For the topical treatment of otitis externa caused by the ear mite *Otodectes cynotis*. The product also has anti-inflammatory and anti-pruritic activity.
ATCvet code	QS02CA01

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 Surolan 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 HPRA considered that Surolan 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 the dose claim of polymyxin B sulphate in the drug product (CRN 7002317)	03/07/2007