IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Oridermyl ear gel

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Oridermyl ear gel
Active substance(s)	Neomycin sulphate Nystatin Triamcinolone acetonide Permethrin 25:75
Marketing authorisation holder	Vetoquinol Ireland Limited First Floor Segrave House 19/20 Earlsfort Terrace Dublin 2
Marketing authorisation number	VPA 10983/40/1
Legal basis of application	Full application in accordance with Article 12(j) of Directive 2001/82/EC as amended.
Date of Authorisation	Original: 1stOctober 1988
Indication and target species	In dogs: For the treatment of mixed ear infections (otitis externa) due to bacteria sensitive to neomycin, yeasts sensitive to nystatin and ear mites (*Otodectes cynotis*) sensitive to permethrin.
Method of sale and supply	POM (Prescription Only Medicine)
Additional supply restrictions	None

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 Oridermyl was assessed before there was a requirement to have a public assessment report. A change to the formulaiton was approved in June 2008 and information relating to this variation are detailed in the relevant sections of this report.

II QUALITY ASPECTS

A post-authorisation application was received for a change to the composition of the product. Permethrin was added; lindane and lidocaine were removed.
The HPRA reference number for this change is CRN: 7004052

The re-formulated product contains the following active substances:
Per g
Neomycin sulphate 3500 IU
Nystatin 100,000 IU
Triamcinolone acetonide 1.0 mg
Permethrin 25:75 10 mg

And the following excipients:
Polyethylene AC6 wax
Liquid paraffin

All relevant quality data required in support of the change in formulation was provided in the dossier.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

Bibliographic data relating to pharmacology and toxicology of each active substance were provided. In a primary study of cutaneous irritation using the finished formulation no irritation was observed.

The applicant provided a user safety assessment in compliance with the relevant guideline which shows that there is no undue risk associated with use of the product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

The applicant provided a Phase 1 environmental risk assessment in compliance with the relevant guideline which shows that no further assessment is required. Warnings and precaution as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV CLINICAL ASSESSMENT (EFFICACY)

III.3.A Pre-Clinical Studies
A.2 Tolerance in the Target Species of Animals
The applicant conducted target animal tolerance studies in healthy dogs using a 1% solution of permethrin alone, and the finished formulation at multiples of the recommended dose. Only evidence of minor, transient irritation was seen with the finished formulation.
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

III.3.B Clinical Studies
B.1 Laboratory Trials
The applicant conducted dose determination studies, using dogs naturally infected with *O cynotis*, to confirm the efficacy of 1% permethrin.
B.2 Field Trials
The applicant conducted a field study in dogs, comparing the new and original formulations of Oridermyl, which show that the formulations were equally safe and effective in controlling natural ear mite infection and secondary signs and infections.

V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the data submitted, the HPRA considered that Oridermyl demonstrated adequate evidence of efficacy for the approved indication(s) as well as a satisfactory risk/benefit profile and therefore granted an amended 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

Summary of change (Application number)	**Approval date**
Change to the composition of the product. Permethrin was added; lindane and lidocaine were removed. (CRN:7004052)	June 2008
Change in the name and/or address of the marketing authorisation holder (CRN 7021600)	August 2015