IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Winter Dip Concentrate for dip emulsion

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Winter Dip Concentrate for dip emulsion
Active substance	Diazinon (Dimpylate) 10% w/v.
Marketing Authorisation Holder	Hygeia Chemicals Limited Oranmore Co. Galway
Date of authorisation	1st October 1989
Target species	Sheep
Indication for use	For the treatment and control of sheep scab (*Psoroptes ovis*) and blowfly in sheep
ATCvet code	QP53AF03

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 Winter Dip Concentrate for dip emulsion 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 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.

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	Approval date
Change to finished product formulation to remove the excipient 'Brennspec 947' and replace with excipients 'Sermul EA 88' and 'Ethylan NS-500 LQ'. HPRA case reference number CRN00C69Y	22/12/2022

Safety/Efficacy Changes

Summary of change	Approval date
The product is a liquid preparation for cutaneous application (sheep dip) containing 10% diazinon (dimpylate). The MAH has submitted a Type IIvariation application for user safety reasons.Part II and III of the dossier is amended to allow for a reusable spillproof complete closed transfer system (CTS) for dispensing the dip.This is in order to removing the potential for spillage and thus avoid contamination of the operator.The dip formulation remains unchanged. The applicant has provided a number of studies to demonstrate that the proposed system is safe, secure, easy and accurate to use. Changes are made to the SPC, labelling, and package leaflet.Separate laminated instructions for use of the CTS are to be supplied with all packs of Dip. HPRA case reference number 7001051	03/08/2006