

IPAR



**Publicly Available Assessment Report for a
Veterinary Medicinal Product**

Ectoflits Summer and Winter Sheep Dip, 60% w/w Concentrate for Dip Solution

PRODUCT SUMMARY

The Public Assessment Report reflects the scientific conclusion reached by the IMB 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 IMB 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 IMB leading to the approval of the product for marketing in Ireland.

PUBLIC ASSESSMENT REPORT

Name, strength and pharmaceutical form	Ectoflits Summer and Winter Sheep Dip 60%w/w Dip Concentrate
Active substance(s)	Dimpylate (Diazinon Stabilised Technical)
Marketing authorisation holder	Bimeda Animal Health Limited 2, 3 & 4 Airton Close Airton Road Tallaght Dublin 24 Ireland
Marketing authorisation number	10960/063/001
Legal basis of application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC as amended.
Date of authorisation	7/11/2006
Indication and target species	Sheep: For the prevention and treatment of Blowfly Strike, Keds, Lice and Scab infestations
Method of sale and supply	LM: as an item for sale or supply only from a pharmacy, from a premises to which an Animal Remedies Merchant's Licence relates, or by a registered veterinary surgeon for the treatment of animals under his/her care.
Additional supply restrictions	None

The Summary of Product Characteristics (SPC) for this product is available on the IMB's website.

I. SCIENTIFIC OVERVIEW

This is an informed consent application on an already authorised veterinary medicinal product, Osmonds Goldfleece Fly and Winter Dip, (VPA10960/9/1). The initial application for the originator medicine was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the IMB considered that Ectoflits Summer and Winter Sheep Dip 60%w/w Dip Concentrate (VPA 10960/63/1) demonstrated adequate evidence of quality, safety and efficacy for the approved indication as well as a satisfactory risk/benefit profile.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet are updated on a continuous basis to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the IMB's website.