IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

NUFLOR Swine 300 mg/ml Solution for injection

PRODUCT SUMMARY

EU Procedure number	(formerly FR/V/0118/001)
Name, strength and pharmaceutical form	NUFLOR Swine 300 mg/ml Solution for injection
Active substances(s)	Florfenicol
Applicant	Intervet Ireland Limited Magna Drive Magna Business Park, Citywest Road Dublin 24 Ireland
Legal basis of application	Full application (Article 12(3) of Directive No 2001/82/EC)
Date of Authorisation	21 March 2013 (IE)
Target species	Pigs
Indication for use	
ATCvet code	QJ01BA90
Concerned Member States	Austria (AT); Belgium (BE); Greece (EL); Italy (IT); Luxembourg (LU); Netherlands (NL); Portugal (PT)

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 the 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.

VI. POST-AUTHORISATION ASSESSMENTS

Summary of change (Application number)	**Approval date**
Introduction of changes to the SPC arising from the outcome of the Article 83 Referral for all veterinary medicinal products containing N-methyl pyrrolidone as an excipient, EMEA/V/A/146, (2023)2311 of 28 Mar 2023.	November 2023