

IPAR



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

Nifencol 300 mg/ml solution for injection for cattle and pigs

PUBLIC ASSESSMENT REPORT**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:**Safety/Efficacy Changes**

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.	19/10/2023