Veterinary Medicines Directorate

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Post Authorisation Assessments

Nuflor Minidose 450 mg/ml Solution for Injection for Cattle

Vm 01708/5096

•	28 April 2024	Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone (NMP) as an excipient. One-off alignment of the product information with version 9.0* of the QRD templates.
•	02 June 2023	Tightening of specification limits for the active substance.
•	15 May 2023	Change excipient test procedure. Minor changes to manufacturing process. Addition of manufacturer responsible for batch release and batch control. Addition of a manufacturing site responsible for secondary packaging. Addition of a manufacturing site for the manufacture of the finished product.
•	09 February 2023	Tightening of specification limits for the active substance.
•	27 January 2022	Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	17 June 2021	Deletion of manufacturing site for an active substance.
•	03 December 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	26 July 2019	Change in the name of the manufacturer of the finished product.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	05 January 2017	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.
•	29 June 2016	Change in the manufacturer of a starting material used in the manufacturing process.
•	08 April 2015	Change in the batch size of the finished product. Change in the address of the ASMF holder. Tightening of specification limits for the active substance.
•	28 November 2014	Update to the DDPS.
•	20 November 2014	Change in test procedure for the active substance. Change in the re-test period of the active substance. To introduce a second manufacturing process.
•	23 December 2013	Renewal procedure – Germany as RMS.

•	26 October 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	02 November 2011	To add the intramuscular route of administration at a dose rate of 20 mg/kg bw to be administered twice, 48 hours apart.
•	13 October 2011	To change the shelf-life specification limits of the active substance and the release and shelf-life limits of related substances.
•	06 July 2011	To tighten the specification limits for the active substance.
•	07 December 2009	To add a manufacturer of the active substance.
•	15 October 2009	To add a manufacturing site.