Veterinary Medicines Directorate

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Post Authorisation Assessments

Nuflor Minidose 450 mg/ml Solution for Injection for Cattle

Vm 01708/3026

March 2025	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
20 January 2025	Substitution of 'metaphylaxis' for 'prevention'.
28 April 2024	Amendment of the product literature to reflect the outcome of the Article 83 referral for products containing NMP. Alignment of the product information with version 9.0 of the QRD template.
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.