Veterinary Medicines Directorate

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Post Authorisation Assessments

Dimazon 50 mg/ml Solution for Injection

Vm 01708/4406

•	25 October 2022	Change for excipient to comply with Ph.Eur.
•	30 December 2020	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	01 July 2019	Change in the name of a manufacturer of the finished product.
•	27 November 2018	Editorial updates to the SPC and package leaflet to improve clarity.
•	22 February 2017	Change in the manufacturing process of the finished product.
•	27 July 2016	Submission of an updated certificate of suitability from an already approved manufacturer. Submission of a new Eur. certificate of suitability for an active substance.
•	19 September 2012	Submission of an updated Part II of the Dossier Changes to formulation Deletion of alternative packaging Change to test performed on the finished product Changes to the specification of the finished product Change of batch size Change of composition of packaging Minor change in manufacture of the finished product
•	29 December 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	04 May 2011	Corrections to section 4.9 of the SPC
•	14 July 2010	Change of component of a packaging component
•	03 December 2009	Renewal
•	27 June 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	01 July 2005	Change of distributor