Veterinary Medicines Directorate

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Post Authorisation Assessments

Narketan-10 100mg/ml Solution for Injection

Vm 08007/4090

•	17 November 2023	Update to the Ph. Eur. CEP.
•	21 December 2022	Deletion of a manufacturer of the active substance.
•	21 December 2022	Submission of a new certificate of suitability.
•	31 May 2019	Changes to the labelling and package leaflet
•	02 May 2018	Change in the address of the marketing authorisation holder from Vetoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS.
•	15 August 2014	Deletion of a secondary packaging site.
•	04 August 2010	Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	22 February 2010	Harmonisation of the SPC
•	14 February 2008	Addition of a manufacturing site of the active substance
•	30 January 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	28 December 2007	Addition of a packaging component
•	13 April 2007	Renewal
•	12 July 2006	Change of batch size Replacement of manufacturing site for all of the manufacturing process Minor change to manufacturing process of the finished product
•	19 April 2006	Addition of a supplier of packaging components
•	21 March 2006	Change of manufacturer of the active substance Change of composition of the primary packaging Change of manufacturing site for batch release
•	04 October 2005	Batch control
•	07 September 2005	Change of importer address
•	19 November 2004	Addition of a manufacturer for assembly of the dosage form
•	25 August 2004	Batch control
•	19 August 2004	Change of address of the MAH
•	27 October 2003	Renewal
•	29 August 2002	Change of importer
•	27 December 2001	Change of name and address of MAH
•	16 October 2001	Change to manufacturer of the dosage form

		Variation to the manufacturer of the active substance Change to test procedures Change of packaging composition Change to specification of the finished product
•	25 September 2001	Change of batch size Change to specification of an active substance
•	29 February 2000	Addition of a safety warning regarding handling of horses during administration