



## Post Authorisation Assessments

### Narketan-10 100mg/ml Solution for Injection Vm 08007/5046

27 June 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
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