Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

# Post Authorisation Assessments

## Narketan-10 100mg/ml Solution for Injection

Vm 08007/5046

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| 15 September 2026 | Changes to the summary of the PSMF not already covered elsewhere in this Annex. |
| 27 May 2026 | One-off alignment of the product information with version 9.0 of the QRD templates. |
| 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<br>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<br>Replacement of manufacturing site for all of the manufacturing process<br>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<br>Change of composition of the primary packaging<br>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 |

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