



Post Authorisation Assessments

Norodine 80 Tablets

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| • | 30 July 2019 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 14 November 2016 | Submission of an updated certificate of suitability. |
| • | 16 July 2013 | Submission of updated EDQM certificates of suitability from already approved manufacturers. |
| • | 29 May 2012 | Change of address of the distributor. |
| • | 20 November 2008 | Changes to the SPC and product literature to bring them into line with new legislation. |
| • | 07 October 2008 | Deletion of an active substance manufacturer. |
| • | 08 May 2008 | Update of an EDQM certificate of suitability for an active substance. |
| • | 03 January 2008 | Addition of an active substance manufacturer. |
| • | 28 December 2007 | Addition of an active substance manufacturer. |
| • | 22 February 2007 | Renewal. |
| • | 20 February 2007 | Change of legal category from POM to POM-V. |
| • | 23 November 2005 | Addition of a site of secondary assembly. |
| • | 18 October 2002 | Renewal. |
| • | 27 September 2000 | Addition of a manufacturer of an active substance. |
| • | 19 October 1999 | Addition of a manufacturer of an active substance. |
| • | 01 May 1998 | Addition of a manufacturer of an active substance. |
| • | 21 January 1998 | Renewal. |
| • | 07 March 1997 | Additions of manufacturers of the active substances. |
| • | 10 October 1996 | Change of active substance manufacturer. |
| • | 10 May 1995 | Addition of a presentation. |