



## Post Authorisation Assessments

### Chanazine 2% Solution for Injection Vm 11990/4005

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|---|-------------------|--|
| • | 01 August 2022    | Substantial changes in the updated version of the ASMF.  |
| • | 29 August 2019    | Increase in batch size of the active substance used in the manufacturing process of the active substance.<br>Tightening of specification limits of a related substance used in the manufacturing process of the active substance.<br>Minor change to the restricted part of an Active Substance Master File.<br>Change in the manufacturer of a starting material used in the manufacturing process of the active. |
| • | 11 June 2018      | Change in the specification limits of the finished product.  |
| • | 05 August 2015    | Minor change in the manufacturing process of the active substance.   |
| • | 24 February 2014  | Change in the manufacturing process of the active, change in test procedure for the active and change to the retest period of the active substance.  |
| • | 03 October 2012   | Update of Active Substance Master File (ASMF)  |
| • | 06 April 2011     | Addition of a new manufacturing site responsible for batch control   |
| • | 17 February 2011  | Addition of a new site for manufacture and primary assembly  |
| • | 11 November 2009  | Update of SPC and Product Literature safety warnings   |
| • | 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  |
| • | 18 May 2006       | Change in test procedure performed on the finished product   |
| • | 04 May 2006       | Renewal  |
| • | 15 November 2001  | Renewal  |
| • | 11 May 2000       | Removal of milk withdrawal period<br>Addition of contraindication for animals producing milk for human consumption   |
| • | 12 March 1998     | Change of manufacturer of the active substance   |
| • | 03 September 1996 | Renewal  |
| • | 20 June 1996      | Change of shelf life   |
| • | 30 May 1996       | Change of manufacturing site of the dosage form  |
| • | 24 May 1996       | Change of operator warnings<br>Addition of target species  |

