



Post Authorisation Assessments

Clinacin 75mg Tablets

Vm 11990/4018

•	28 January 2022	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms.
•	15 October 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance. Deletion of Ph. Eur. certificates of suitability for an active substance.
•	17 February 2020	Deletion of a non-significant specification parameter of the finished product.
•	22 March 2019	Change in the shelf-life of the finished product stored in HDPE containers to 5 years
•	20 October 2016	Submission of an updated certificate of suitability.
•	26 February 2015	Submission of a new Ph. Eur. Certificate of Suitability for an active substance, from an already approved manufacturer.
•	06 May 2014	Deletion of a Ph. Eur. Certificate of Suitability for the active substance.
•	09 November 2009	Submission of a new Ph. Eur. Certificate of Suitability for an active substance from a new manufacturer
•	19 December 2008	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	27 August 2008	Change of address of a manufacturer of the active substance
•	07 February 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	06 December 2007	Renewal
•	15 August 2006	Change in manufacturing process of the finished product
•	25 July 2006	Change in batch size of the finished product
•	28 October 2005	Addition of 10, 16, 20, 30 and 80 tablet pack sizes
•	26 November 2004	Addition of a manufacturer of the active substance
•	12 September 2003	Change of shelf life from 24 months to 36 months
•	18 March 2003	Addition of a 100 tablet pack size
•	23 October 2002	Change of specification of the active substance

•	21 October 2002	Change of shelf life from 12 months to 24 months
•	30 April 2001	Change of type of non-sterile containers