



Post Authorisation Assessments

Clinacin 75mg Tablets

Vm 11990/4018

03 April 2025	Change in the finished product test procedure to comply with Ph. Eur.
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