



Post Authorisation Assessments

Buscopan Compositum Solution for Injection Vm 08327/4292

•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	28 September 2022	Change(s) in the SPC, to sections 4.5, 4.6 and 4.8 and corresponding labelling or package leaflet.
•	05 August 2022	Updated certificate of suitability from an already approved manufacturer.
•	30 May 2022	Deletion of manufacturing site for a finished product.
•	12 April 2022	Reduction of the shelf life of the finished product as packaged for sale from 48 months to 36 months.
•	30 October 2019	Update to the adverse events sections of the SPC and package leaflet.
•	21 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	09 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	28 March 2018	Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers. Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers. Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers. Deletion of a non-significant specification parameter of the finished product. Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers. Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers.
•	15 June 2017	Addition of a site where batch control/testing takes place Addition of a site where batch control/testing takes place
•	10 December 2014	Addition of manufacturing sites for parts of the manufacturing process. Addition of a site for batch control/testing.

		<p>Addition of a site responsible for batch release.</p> <p>Changes to the manufacturing processes of the finished product.</p> <p>Change in the batch size of the finished product.</p> <p>Deletion of non-significant in-process tests applied during the manufacture of the finished product.</p> <p>Changes to in-process tests applied during the manufacture of the finished product.</p>
•	01 November 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	12 October 2012	Addition of a new specification for the finished product along with a new test method performed on the finished product.
•	01 March 2012	Deletion of an assembly site.
•	09 February 2012	Deletion of a manufacturing site of an active substance, finished product and product assembly.
•	03 October 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	17 August 2011	Harmonisation of updated SPC and Product Literature.
•	03 November 2009	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	09 April 2008	Submission of two updated Ph. Eur. Certificate of Suitability for the active substances from an already approved manufacturer.
•	17 August 2006	Changes to bring the SPC and Product Literature in line with new legislation.
•	17 August 2006	Renewal.
•	05 April 2006	Submission of two new Ph. Eur. Certificates of Suitability for active substance from a manufacturer not already approved.
•	15 September 2005	Increase of withdrawal period for horses to 12 days. Removal of calves from the target species.
•	18 December 2003	Change of test method performed on the finished product.
•	31 October 2003	Change in specification of the finished product.
•	25 June 2003	Change of name of the site of batch release.
•	07 August 2002	Change in batch size of the finished product.
•	23 October 2001	Harmonisation of the UK SPC with IE.
•	18 June 2001	Changes to the finished product specification.
•	29 January 2001	Review.