



Post Authorisation Assessments

Epiphen 30 mg Tablets Vm 08007/5016

23 June 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
30 December 2022	Changes in the SPC, labelling or package leaflet, to sections 4.3, 4.4, 4.5, 4.6, 4.7, 4.8.
10 November 2022	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Minor change in the manufacturing process.
10 November 2022	Changes to the quality part of the dossier: Deletion of a non-significant in-process test during the manufacturing of the finished product.
02 May 2018	Change in the address of the marketing authorisation holder from Vetoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS.
07 September 2016	Submission of an updated certificate of suitability.
19 November 2015	Changes to the mock-ups
10 November 2015	Submission of an updated Ph. Eur. Certificate of Suitability.
28 October 2015	Change in dimensions of the container. (immediate packaging)
17 October 2014	Submission of an updated Ph. Eur. Certificate of Suitability.
28 June 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
13 November 2012	Change of composition of the immediate packaging
27 October 2010	Addition of storage condition to the SPC
14 September 2010	Addition of a manufacturer of the active substance Submission of 2 Ph. Eur. Certificates of Suitability for an active substance
05 May 2010	Addition of a manufacturer and assembler of the finished product
25 March 2010	Addition of a manufacturing site of batch release Increase of batch size
16 September 2009	Minor change to the manufacturing process of the finished product
10 June 2009	Submission of an updated Active Substance Master File (ASMF)
17 March 2009	Change of specification of the finished product
27 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
16 October 2007	Change of manufacturer and assembler of the dosage form
25 April 2006	Change of site of batch release
01 March 2006	Renewal
10 December 2004	Change of address of the MAH and Distributor
07 September 2001	Renewal
15 May 2000	Change of manufacturing site and site of assembly
26 June 1996	Change of MAH