



## Post Authorisation Assessments

### Epiphen Solution 4% w/v, Oral Drops

Vm 08007/4081

•	30 August 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	05 January 2023	Change(s) in the SPC, labelling or package leaflet, to sections 4.3, 4.4, 4.5, 4.6, 4.7, 4.8.
•	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.
•	01 February 2017	Increase in batch size of the finished product. Minor change in the manufacturing process of the finished product. Addition of a manufacturer responsible for batch release. Addition of a secondary manufacturing site of the finished product. Addition of a primary manufacturing site of the finished product. Submission of a new Ph. Eur. certificate of suitability. Change in test procedure for the finished product. Addition of a manufacturing site of the finished product. Submission of a new Ph. Eur. certificate of suitability.
•	03 June 2016	An increase in shelf life from 18 months to 2 years.
•	28 June 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	13 July 2011	Change of finished product release and finished product shelf life specification for an excipient
•	16 March 2010	Change to specification of the finished product
•	13 January 2010	Modification of the dosing device
•	13 November 2009	Batch Control
•	10 June 2009	Submission of an updated Active Substance Master File (ASMF)
•	23 October 2008	Renewal
•	03 July 2008	Change of dispensing mechanism on primary packaging of 30ml presentation
•	28 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
•	23 November 2005	Change of address of site of batch release

•	22 December 2004	Change of address of the MAH
•	08 November 2002	Change to dropper insert – 30ml for 2kg dog dropper from 3-5 drops per day to 4-7 drops per day. 30ml for 5kg dog dropper from 6-12 drops per day to 8-16 drops per day
•	08 February 2002	Additional manufacturer and assembler of the dosage form