



Post Authorisation Assessments

Amoxycare Suspension for Injection 15% w/v

•	01 April 2022	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	27 May 2021	Deletion of a non-significant specification parameter of an excipient.
•	27 January 2021	Reduction of the shelf life of the finished product as packaged for sale from 2 years to 12 months. Reduction of the shelf life of the finished product as packaged for sale from 2 years to 12 months.
•	18 September 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	02 August 2018	Increase in batch size of the finished product. Increase in batch size of the finished product.
•	10 July 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph. Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	13 July 2016	Changes to a test procedure for the finished product.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	20 October 2014	Change to the name of an excipient, from 'Coconut Oil, Fractioned' to 'Propylene Glycol Dicaprylocaprate'.
•	26 July 2013	Change in distributor details
•	16 May 2013	Addition of a pack type – plastic vials.
•	18 April 2013	Submission of a new/updated Ph. Eur. Certificate of Suitability.
•	16 December 2008	Change in SPC/product literature to bring in line with new legislation.
•	17 July 2008	Addition of a manufacturing site for the active substance.
•	02 August 2007	Renewal.
•	19 March 2007	Change of legal category from POM to POM-V.
•	11 August 2005	Addition of a site of assembly.
•	21 March 2003	Renewal. Addition of a manufacturer for an active substance.
•	26 November 1998	Extension for use in food producing species. Change in withdrawal period.

