



## Post Authorisation Assessments

---

### Amoxycare 40mg Tablets

|   |                   |   |
|---|-------------------|---|
| • | 30 July 2019      | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 26 July 2013      | Change of distributor details.  |
| • | 18 April 2013     | Submission of an updated Ph. Eur. Certificate of Suitability for an already approved active substance manufacturer.   |
| • | 11 September 2012 | Submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active substance.   |
| • | 10 December 2008  | Change to bring SPC and labels in line with new legislation.  |
| • | 18 May 2007       | Renewal.  |
| • | 19 March 2007     | Change of legal category from POM to POM-V.   |
| • | 11 August 2005    | Addition of site of assembly.   |
| • | 18 June 2003      | Renewal.  |
| • | 20 March 2003     | Addition of manufacturing sites for the active substance.   |
| • | 28 May 1998       | Change in pack size.  |