



Post Authorisation Assessments

Pentoject, Pentobarbitone Sodium 200 mg/ml Solution for Injection Vm 32742/4033

| | | |
|---|-------------------|---|
| • | 27 June 2024 | Change in the shelf-life or storage conditions of the finished product: - Other changes. Change in immediate packaging of the finished product: - Qualitative and quantitative composition - Sterile medicinal products. |
| • | 22 December 2023 | Approval of mock ups. |
| • | 03 March 2023 | Removal of Ph.Eur. reference in finished product specification due to changes in updated monograph. |
| • | 11 August 2022 | Change of MAH: from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB, United Kingdom to Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium. |
| • | 07 June 2022 | Change to increase the maximum batch size of the finished product. |
| • | 11 March 2019 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 27 September 2018 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of 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. |
| • | 12 June 2018 | Change in the number of units (e.g. tablets, ampoules, etc.) in a pack within the range of the currently approved pack sizes of the finished product. Deletion of manufacturing site for an active substance, finished product, manufacturer responsible for batch release. Submission of a new Ph. Eur. certificate of suitability for an active substance used in manufacturing process of active) / excipient from a new manufacturer. Addition in-process controls applied during the manufacture of the finished product. Change in the manufacturer of a starting material of the active where no Ph. Eur. Certificate of Suitability is part of the approved dossier. To add site of finished product manufacture, assembly, batch testing and batch release. |
| • | 24 April 2015 | Change in immediate packaging of the finished product. |
| • | 26 February 2015 | Change in distributor details. |

| | | |
|---|------------------|---|
| • | 21 June 2013 | Variation to update the Marketing Authorisation Holder. |
| • | 19 March 2008 | Renewal. |
| • | 03 February 2005 | Renewal. |
| • | 31 October 2001 | Change in the name of the Manufacturer/Assembler of the finished product. |
| • | 31 October 2001 | Addition of a Manufacturer of the finished product. Addition of an Assembler of Dosage Form. |
| • | 21 June 2001 | Addition of an Active Substance Manufacturer. |
| • | 28 January 1999 | Renewal. |
| • | 19 October 1998 | Change of name of Marketing Authorisation Holder. |