Veterinary Medicines Directorate

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Post Authorisation Assessments

Pentoject, Pentobarbitone Sodium 200 mg/ml Solution for Injection

Vm 32742/4033

•	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.