Veterinary Medicines Directorate

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Post Authorisation Assessments

Juramate 250 µg/ml Solution for Injection

Vm 25296/4001

•	08 June 2020	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.
•	11 October 2019	Renewal – National.
•	22 February 2019	Replacement of a manufacturer responsible for batch release of the finished product.
•	22 February 2019	Change in distributor details. From Bimeda, a division of Cross Vetpharm Group UK Limited, Bryn Cefni Industrial Park, Llangefni, Anglesey, LL77 7XA, U.K. to Jurox (UK) Limited, Second Floor, Richmond House, 105 High Street, Crawley, West Sussex, RHD 1DD, U.K.
•	30 August 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	16 August 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	16 September 2016	Change of MAH address.
•	25 April 2013	To increase the batch size of the finished product by up to 10-fold.
•	25 April 2013	To change the manufacturing process of the finished product.
•	25 February 2013	To change the name and address of the Marketing Authorisation Holder from Jurox (UK) Plc to Jurox (UK) Limited.
•	20 June 2012	Introduction of a new pharmacovigilance system.
•	04 April 2012	To change the distributor details.
•	28 March 2012	To change the manufacturer responsible for batch release.
•	28 March 2012	To add an additional manufacturer responsible for batch release
•	30 March 2011	To change the shelf life of the finished product from 2 years to 3 years.
•	03 June 2009	To change the distributor.
•	21 May 2009	To change the address of the Marketing Authorisation Holder