



Post Authorisation Assessments

Marbox 100 mg/ml Solution for Injection for Cattle and Pigs Vm 15052/4048

•	October 2022	Addition of manufacturing site responsible for radiosterilisation of plastic vials.
•	14 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	12 November 2020	Submission of a new certificate of suitability for an active substance.
•	22 November 2019	Replacement of a specification parameter with its corresponding test method of the finished product.
•	17 January 2018	Addition of a second manufacturing site responsible for the radio sterilisation.
•	22 December 2017	Minor change in the manufacturing process of an immediate release solid oral dosage form* or oral solutions. Change to in-process tests or limits applied during the manufacture of the finished product.
•	21 December 2017	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.
•	19 September 2017	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.
•	06 January 2016	Submission of an updated DDPS.
•	08 October 2015	Renewal – UK as CMS
•	15 July 2015	Change in batch size of the active substance. Change in test procedure for the active substance. Changes in the manufacturing process of the active substance.
•	13 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
•	11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
•	13 February 2012	To change the UK Marketing Authorisation Holder address.
•	06 January 2012	To change the name and address of the Marketing Authorisation Holder in Italy only

•	28 June 2011	To add a new manufacturer of the active substance.
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