



Post Authorisation Assessments

Marbodug 100 mg/ml Solution for Injection for Cattle and Pigs

Vm 34534/4009

•	04 May 2024	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (NI)
•	27 March 2024	Updated CEP submitted for the manufacture of an active substance. (GB)
•	11 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	22 June 2022	Updated certificate of suitability from an already approved manufacturer.
•	01 December 2020	Change in the invented name of the veterinary medicinal product from Marbocare 100 mg/ml Solution for Injection for Cattle and Pigs to Marbodug 100 mg/ml Solution for Injection for Cattle and Pigs in UK and IE.
•	11 June 2020	Introduction of a new pharmacovigilance system. Change in distributor details from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB to DUGV (UK) Limited, Union House, 111 New Union Street, Coventry, CV1 2NT. Change of MAH, from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB to Emdoka bvba, John Lijzenstraat 16, B-2321 Hoogstraten , Belgium.
•	17 February 2020	Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 October 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.
•	16 April 2018	Change of RMS from UK to IE.
•	29 December 2017	Renewal UK as RMS.
•	26 February 2015	Change in distributor details.
•	08 August 2013	Change in the address of the Marketing Authorisation Holder and change to the QPPV contact details.

