Veterinary Medicines Directorate

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Post Authorisation Assessments

Isaderm 5 mg/g + 1 mg/g Gel for Dogs

Vm 24883/5000

•	03 November 2023	Change in test procedure for the finished product.
•	29 September 2023	Approval of mock ups.
•	29 August 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability. (NI only)
•	12 June 2023	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability. (GB only)
•	13 January 2023	Minor changes to an approved test procedure for the finished product.
•	13 October 2022	Minor change in the manufacturing process of the finished product.
•	12 July 2022	Minor changes to an approved test procedure for the finished product.
•	26 May 2022	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 April 2022	Addition of a site where batch control/testing takes place.
•	15 August 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 July 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	30 May 2019	Renewal – UK as CMS
•	12 February 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	16 July 2018	Change in RMS from UK to IE.
•	08 February 2018	Repeat Use application to add 4 new member states.
•	03 August 2017	Deletion of Ph. Eur. certificates of suitability for an active substance.
•	25 May 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	10 February 2017	Submission of a new certificate of suitability.
•	01 November 2016	Mock-ups approved.

•	30 April 2015	Change in the batch size of the finished product. Minor change in the manufacturing process of the finished product.