Veterinary Medicines Directorate

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Post Authorisation Assessments

Clavudale 400 mg / 100 mg Tablets for Dogs

Vm 10434/5016

•	28 April 2024	One-off alignment of the product information with version 9.0 of the QRD templates.
•	15 November 2022	Change in the immediate packaging of the finished product - increase in thickness of the blister foil.
•	04 November 2022	Submission of a new certificate of suitability.
•	20 January 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 September 2021	Deletion of Ph. Eur. certificates of suitability for an active substance (used in manufacturing process of active).
•	12 January 2021	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. 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.
•	07 January 2021	Addition of a manufacturer responsible for batch release of the finished product.
•	28 October 2020	Change in the number of units (tablets) in a pack outside the range of the currently approved pack sizes of the finished product.
•	26 August 2020	Increase in batch size of the finished product.
•	11 August 2020	Addition of a secondary packaging site of the finished product.
•	07 July 2020	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	6 May 2020	Repeat Use application to add 9 new member states.
•	23 October 2019	Repeat Use application to add 2 new member states.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	01 August 2018	Change in the RMS from UK to IE.

•	13 July 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	13 July 2017	Deletion of manufacturing site for an active substance.
•	03 June 2016	Submission of a new certificate of suitability.
•	03 June 2016	Submission of a new certificate of suitability.
•	25 June 2015	Renewal – UK as RMS.
•	16 October 2014	Change to the style of packaging - approval of updated mock-ups.
•	15 August 2014	Change in MAH address. Change in address of the local representative in Belgium, Luxembourg and The Netherlands.
•	27 June 2014	Changes to the composition of the finished product.
•	05 January 2012	Submission of new Ph. Eur. certificates of suitability; to add new manufacturers.
•	06 January 2011	To change the distributor.