Veterinary Medicines Directorate

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Post Authorisation Assessments

Eraquell 18.7mg/g Oral Paste

Vm 05653/3013

•	15 November 2021	Change to update the local representative for Ireland for all presentations. Changes to the labelling.
•	07 May 2021	Deletion of a non-significant specification parameter of the finished product.
•	09 July 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	21 January 2019	Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	05 December 2018	Increase in batch size of the finished product. Changes in the manufacturing process of the finished product.
•	13 July 2016	Deletion of a non-significant specification parameter. Submission of an updated Ph. Eur. certificate of suitability for an active substance.
•	9 December 2015	Change in legal entity of the MAH, from 'Virbac de Portugal Laboratórios Lda' to 'Virbac, France'.
•	27 August 2015	Submission of a new certificate of suitability from a new manufacturer.
•	25 October 2011	Approval of previously unseen mock-ups.
•	29 June 2011	Approval of previously unseen mock-ups.
•	23 February 2011	Change to the address for the MAH and submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer. Also addition of a manufacturer responsible for primary and secondary packaging and addition of a manufacturer responsible for batch release.
•	24 November 2010	Addition of a manufacturing site for all of the manufacturing process of the finished product.
•	09 June 2010	Renewal.
•	31 January 2006	Change of batch size.
•	19 April 2005	Addition of a new presentation – 7.49g syringes.
•	08 April 2005	Addition of a new pack size.
•	30 December 2004	Renewal.
•	07 May 2004	Submission of an updated Ph Eur. Certificate of Suitability for an active substance from an already approved manufacturer.