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Post Authorisation Assessments

Enacard Tablets for Dogs 10 mg

•	28 May 2020	Change in the name of a manufacturer of the finished
	04 November 2040	product, also responsible for batch release.
•	01 November 2018	Change in the name and address of the marketing
		authorisation holder from Merial Animal Health Ltd,
		Sandringham House, Sandringham Avenue, Harlow
		Business Park, Harlow, Essex, CM19 5TG to Boehringer
		Ingelheim Animal Health UK Ltd, Ellesfield Avenue,
		Bracknell, Berkshire, RG12 8YS.
•	10 December 2014	Addition of a manufacturer of the active substance,
		supported by a new Ph. Eur. Certificate of Suitability.
		Replacement of a test for the active substance.
•	26 November 2009	Change of storage conditions from 'Do no store above
		30°C' to 'Do not store above 25°C'.
•	09 September 2008	Renewal.
•	28 August 2008	Change in test procedure performed on the finished
	00.4 1.0000	product.
•	08 August 2008	Change in test procedure performed on the finished
	45 1 1 0000	product.
•	15 July 2008	Addition of a manufacturing site for all of the
		manufacturing process of the finished product.
		Minor change in the manufacturing process of the
	40.14 0000	finished product.
•	13 May 2008	Addition of a new manufacturer responsible for batch
		control and testing.
		Deletion of a packaging site for the blister presentation.
	40 Amril 2007	Deletion of a batch release site for the finished product.
•	18 April 2007	Change of legal category from POM to POM-V.
		Changes to the SPC and Product Literature to bring in
	04 November 2004	line with new legislation. Addition of a site of batch release.
•	04 NOVEITIBEL 2004	Addition of a manufacturer for assembly of the blister
		presentation.
•	13 February 2004	Renewal.
•	22 January 2004	Minor changes to the specification of the active
		substance.
		Minor changes to methods of control for the finished
		product.
•	10 October 2003	Minor changes to the manufacturing process of the
		active substance.
•	01 January 2001	Change of in use shelf life.
•	07 December 2000	Change of finished product specification.
•	21 June 2000	Change of product name from 'Enalfor Tablets for Dogs'
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		to 'Enacard Tablets for Dogs'.
•	10 December 1999	Additional manufacturing sites for the assembly of the
		dosage form.
•	17 March 1999	Addition of pack type.
•	30 July 1998	Renewal.
•	10 January 1996	Change to the manufacturing process of the finished product.
		QC Procedure.
•	31 May 1995	Change to indications.