Veterinary Medicines Directorate

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Post Authorisation Assessments

Corvental D 200 mg Hard Capsules

Vm 00879/4015

•	16 October 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	11 February 2020	Submission of an updated Ph. Eur. TSE certificate of suitability. Deletion of Ph. Eur. TSE certificates of suitability.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	10 October 2018	Submission of a new Ph. Eur. TSE certificate of suitability for a starting material already approved manufacturer. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Deletion of Ph. Eur. TSE certificates of suitability for an active substance (used in manufacturing process of active).
•	31 October 2017	Deletion of a supplier of packaging components or devices.
•	09 August 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	27 September 2016	Deletion of a manufacturing site. Submission of an updated certificate of suitability. Submission of an updated certificate of suitability.
•	13 January 2016	Change of Marketing Authorisation Holder from Novartis Animal Health UK Ltd to Elanco Europe Ltd. Change in distributor details.
•	13 March 2015	Change in the specification parameters and limits of the finished product. Addition of a manufacturing site responsible for part of the manufacturing process, batch control and batch release.
•	23 July 2014	Addition of a manufacturing site for primary and secondary packaging.
•	14 October 2013	Change in pack size Change to manufacturing site responsible for batch release and quality control testing of the finished product

•	21 August 2012	Submission of updated Ph. Eur. Certificates of Suitability for an excipient Deletion of two manufacturing sites Change of inks used on the finished product
•	16 June 2010	Submission of updated Ph. Eur. Certificates of Suitability for excipients
•	14 April 2010	Change of storage conditions from 'Do not store above 25˚C' to 'Do not store above 30˚C'
•	31 October 2008	Addition of batch release and testing site
•	08 October 2008	Submission of updated Ph. Eur. Certificates of Suitability for excipients
•	28 August 2008	Approval of previously unseen mock ups
•	21 August 2008	Corrections to the Product Literature
•	31 July 2008	Change in finished product composition
•	07 July 2008	Change in name of manufacturer and assembler of the dosage form
•	17 April 2008	Addition of a 100 capsule pack size Minor changes to the pack details on the SPC Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	19 March 2008	Addition of an assembler of the dosage form
•	07 December 2007	Change of MAH address Change of distributor address
•	29 August 2007	Renewal
•	03 August 2007	Submission of an updated ph. Eur. Certificate of Suitability for the active substance from an already approved manufacturer
•	20 July 2007	Change in test procedure performed on the finished product
•	13 June 2007	Change to in-process tests performed on the finished product
•	03 April 2007	Change of composition of printing ink for capsule shell Change in specification of excipients to comply with Ph. Eur.
•	26 March 2007	Change in name of manufacturer and assembler of the dosage form
•	08 August 2006	Submission of updated Ph. Eur. Certificates of Suitability for excipients Submission of updated Ph. Eur. Certificates of Suitability for the active substance
•	16 March 2006	Change in test procedure performed on the finished product Change in specification of the finished product
•	31 January 2006	Change in finished product specification Change in active substance specification Submission of an updated Ph. Eur. Certificate of Suitability for an excipient Change of manufacturer of the active substance
•	21 December 2005	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	23 March 2004	Renewal

•	23 November 2000	Change of MAH
•	14 January 2000	Change in finished product specification
•	07 December 1998	Change of manufacturer of the active substance
•	24 February 1998	Renewal
•	29 January 1998	Change of name of manufacturing site of assembly and importing