



Post Authorisation Assessments

Corvental D 500 mg Hard Capsules

Vm 52127/3012

30 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
28 March 2025	Change in legal entity from Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, D-27472 Cuxhaven, Germany.
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
23 June 2010	Submission of an updated Ph. Eur. Certificate of Suitability for an excipient
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
07 December 1998	Change of manufacturer of the active substance