



Post Authorisation Assessments

Lectade Plus Powder for Oral Solution Vm 52127/5068

29 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
12 March 2025	Change of Marketing Authorisation Holder 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.
15 February 2024	One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.
28 February 2022	Change in distributor details from Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ and UniDrug Distribution Group Ltd, Amber Park, Berristow Lane, South Normanton, Alfreton, Derbyshire, DE55 2FH to Elanco UK AH Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, UK.
20 May 2021	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Addition to a test procedure for the finished product.
14 October 2020	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place.
01 October 2020	Change of Marketing Authorisation Holder from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
03 July 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
02 March 2020	Change in test procedure for the finished product.
12 July 2019	Deletion of manufacturing site for finished product.
12 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
16 March 2015	Minor change in the immediate packaging of the finished product.
03 February 2015	Minor change in the manufacturing process of the finished product.
24 June 2014	Change in the name of the manufacturer of the finished product.

08 May 2014	Addition of a site of manufacture of the finished product including primary packaging, secondary packaging and batch release.
05 December 2012	Variation to change shelf-life of veterinary medicinal product as packaged for sale.
30 March 2011	Variation to change the Marketing Authorisation Holder.
07 July 2010	Variation to make a minor change in the manufacturing process of the finished product.
07 July 2010	Variation concerning the addition of an alternating manufacturing site for the finished product.
10 May 2010	Change in the batch size of the finished product.
10 May 2010	Variation to change the composition of the immediate packaging material.
23 July 2008	Renewal.
20 February 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from GSL to AVM-GSL.
25 June 2004	Renewal.
14 March 2003	Renewal.
27 February 1997	Change in the Marketing Authorisation Holder.
13 November 1996	Additional manufacturer of dosage form.