Veterinary Medicines Directorate

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Post Authorisation Assessments

Dectomax 10 mg/ml Solution for Injection for Pigs

Vm 00879/4200

12 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
15 December 2023	Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for the finished product. (NI)
03 February 2023	Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for the finished product.
29 March 2022	Change in the name of the manufacturer of the finished product.
16 February 2022	Change in distributor details from distributors Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT139NJ and UniDrug Distribution Group Ltd, Amber Park, Berristow Lane, South Normanton, Derbyshire, DE55 2FH to Elanco UK AH Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
19 October 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation.
23 December 2020	Change of MAH, 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.
20 August 2020	Change in the name of the manufacturer of the finished product.
28 April 2020	Addition of a site where batch control/testing takes place. Deletion of manufacturing site for a finished product.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
19 February 2019	Addition of a manufacturer responsible for batch release of the finished product.
23 May 2018	RMS change from UK to DE
28 July 2016	Minor change in the manufacturing process of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product.

03 April 2014	Changes to an existing pharmacovigilance system.
03 January 2014	Changes to the SPC and product literature following an EU Directive.
06 September 2013	Change of vial size from 200 ml to 250 ml.
21 June 2013	Addition of a finished product manufacturer, responsible for primary packaging, secondary packaging and batch release and change in the batch size of the finished product.
13 June 2013	Change of MAH address
20 December 2012	Addition of manufacturing sites for secondary packaging
20 September 2012	Addition of test procedures performed on the finished product
14 September 2012	Deletion of non-significant test performed during the manufacture of the finished product
01 December 2011	Change of product name from 'Dectomax Injection for Pigs' to 'Dectomax 10mg/ml Solution for Injection for Pigs'
30 December 2010	Change of address of manufacturing site of the finished product
22 December 2010	Change of MAH
08 May 2009	Renewal
25 July 2007	Change of legal category from PML to POM-VPS
22 May 2007	Change of address of manufacturer of the finished product
30 June 2005	Change of distributor
08 June 2005	Change in batch size of the finished product Change of stability conditions
28 January 2005	Renewal
10 December 2004	Addition of a manufacturing site of the finished product
28 January 2004	Minor change in test procedure of an excipient
05 October 2000	Change of withdrawal period
18 June 1998	Mutual recognition procedure, UK as RMS