Veterinary Medicines Directorate

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Post Authorisation Assessments

Dectomax 5mg/ml Pour-on Solution for Cattle

Vm 00879/4201

•	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.
•	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.
•	22 January 2020	Addition of a site where batch control testing takes place. Deletion of manufacturing sites for a finished product.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	26 April 2019	Change to importer, batch release arrangements and quality control testing of the finished product
•	19 March 2018	Change in RMS from UK to FR.
•	07 August 2014	Change to the labelling and package leaflet, in line with a Commission Decision and the approved QRD text.
•	03 April 2014	Changes to an existing pharmacovigilance system.
•	30 December 2013	Changes to the SPC and product literature following an EU Directive.
•	15 August 2013	Change to comply with Ph. Eur.
•	13 June 2013	Change in address of MAH.
•	12 April 2013	Addition of a manufacturing site for all manufacturing processes of the finished product. Change of batch size of the finished product. Change in immediate packaging of the finished product.
•	14 September 2012	Removal of a parameter from an in-process test performed during the manufacture of the finished product.
•	01 December 2011	Change of product name from ‘Dectomax Pour-on for Cattle’ to ‘Dectomax Pour-on Solution for Cattle 5mg/ml’.
•	22 December 2010	Change of MAH.
•	28 May 2010	Change of manufacturer of the packaging.
•	25 June 2008	Renewal.
•	05 July 2007	Addition of a manufacturing site for all manufacturing operations except batch release.
•	19 June 2007	Change of batch size of the finished product.

•	09 October 2006	Addition of a manufacturing site responsible for batch control.
•	15 February 2006	Change of test procedure performed on an excipient.
•	24 August 2005	Addition of a 3L pack size.
•	28 June 2005	Change of distributor.
•	21 October 2004	Change in manufacturing process.
•	28 May 2003	Renewal.
•	14 October 2002	Change of manufacturer of packaging component.
•	19 July 2001	Repeat use procedure.
•	25 July 2000	Addition of two parasitic target species.
•	22 June 2000	Change of type of non-sterile containers.
•	25 April 2000	Change of shelf life from 36 months to 48 months.
•	03 September 1999	Change of type of non-sterile containers.
•	24 August 1999	Addition of duration of activity against lice species to indications.
•	10 June 1999	Change of size of sterile containers. Change of shelf life.
•	06 July 1998	Update of licence particulars.
•	17 December 1997	Decentralised Procedure, UK as RMS.