Veterinary Medicines Directorate

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Post Authorisation Assessments

Domitor 1 mg/ml Solution for Injection

Vm 06043/4003

•	15 March 2023	Deletion of a non-significant specification parameter of the active substance. Minor changes to an approved test procedure for active substance.
•	15 March 2023	Change in the specification parameters and/or limits of an active substance.
•	27 January 2020	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	15 August 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the safety database of an existing pharmacovigilance system as described in the DDPS. Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	09 May 2019	Changes to the quality control testing arrangements for the active substance – addition of a site where batch control testing takes place.
•	15 June 2018	Change in distributor details. From Vetoquinol UK Limited, Vétoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA, United Kingdom to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northants, NN12 7LS.
•	03 May 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	21 June 2016	Change in the in-use shelf-life of the finished product from 28 days to 3 months. Change in storage conditions of the finished product.
•	14 October 2015	Changes in test procedure for the active substance; change in specification limits of the active substance.
•	02 February 2015	Updates to the SPC and product literature.
•	16 January 2015	Change in distributor details.

•	12 November 2014	Change of distributor.
•	24 January 2014	Change to part of the primary packaging material not in contact with the finished product.
•	08 July 2013	Change to in-process test performed during manufacture of the finished product
•	02 May 2012	Change of distributor
•	21 April 2010	Change of distributor
•	09 December 2009	Addition of warnings regarding alpha 2-adrenoreceptor agonists to the SPC and Product Literature
•	15 September 2009	Change of packaging component
•	08 August 2008	Renewal
•	19 June 2008	Change of name and address of manufacturer and assembler of the dosage form
•	02 November 2007	Change of batch size of the active substance Minor change to the manufacturing process of the active substance
•	16 October 2007	Change in test procedure performed on the active substance
•	27 June 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	24 June 2005	Change of distributor
•	21 January 2005	Renewal
•	26 March 2004	Change of name of manufacturer of the active substance
•	27 December 2001	Change to test method performed on the finished product
•	21 February 2001	Change to test procedure performed on the active substance Change to specification of the active substance
•	24 May 1999	Renewal
•	28 September 1998	Additional presentation
•	02 June 1998	Renewal
•	22 May 1998	Change of specification of ingredients of the finished product
•	20 March 1998	Change of name and address of MAH
•	29 September 1997	Changes to section 4 of the SPC to allow for use in combination with Saffan
•	24 September 1997	Change to therapeutic indications
•	14 October 2015	Minor changes to a method for the active substance Change to the analytical test method Change in a test method Tightening of specification limits