Veterinary Medicines Directorate

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Post Authorisation Assessments

Domosedan 10 mg/ml Solution for Injection for Horses and Cattle

Vm 06043/5006

June 2026	Minor change to an approved test procedure for an active substance. Deletion of a non-significant specification parameter for a reagent used in the manufacture of an active substance. Addition of a new specification parameter for a reagent used in the manufacture of an active substance.
26 February 2025	Harmonisation of Part II of the dossier following an SPC harmonisation procedure.
26 February 2025	Harmonisation of product information after an SPC harmonisation procedure for the same product in the EU.
04 May 2023	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
26 June 2020	Increase in the shelf-life of the finished product after first opening, from 28 days to 3 months. Change in storage conditions of the finished product to 'This medicinal product does not require any special storage conditions. Do not refrigerate or freeze. Keep vials in the outer carton'.
27 January 2020	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
07 October 2019	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, United Kingdom.
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.
02 August 2016	Change in test procedure for the active substance. Change in test procedure for the finished product.
02 February 2015	Updates to the SPC and product literature.
16 January 2015	Change in distributor details.
11 November 2014	Change of distributor.
29 August 2014	Change in the batch size of the finished product.
09 June 2014	Change in the batch size of the finished product.
24 January 2014	Change to part of the primary packaging material not in contact with the finished product.
21 April 2010	Change of distributor.
09 December 2009	Addition of warnings regarding alpha 2-adrenoreceptor agonists to the SPC and Product Literature.
21 October 2009	Renewal.
05 February 2009	Change to packaging component.
19 June 2008	Change of name and address of the manufacturer and assembler of the dosage form.
02 November 2007	Minor change to the manufacturing process of the active substance.
25 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.
12 July 2005	Renewal.
24 June 2005	Change of distributor.
26 May 2005	Change of shelf life from 3 years to 5 years.
14 January 2005	Change of withdrawal period from ‘not for use in Horses for human consumption’ to zero days.
29 October 2004	Change of manufacturing process of the finished product. Change to batch size.
26 March 2004	Change of name of manufacturer of the active substance.
30 December 2003	Change of batch size.
20 March 2003	Renewal.
15 February 2002	Change to test method performed on the finished product.
05 March 2001	Change to specification of the active substance. Change to test procedure performed on the active substance.
22 May 1998	Change to ingredient specification.
12 March 1998	Change of name and address of MAH.
26 February 1998	Renewal.
12 September 1997	Change to therapeutic indications.