Veterinary Medicines Directorate

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Post Authorisation Assessments

Domosedan Gel 7.6 mg/ml Oromucosal Gel

Vm 06043/4001

09 July 2026	Minor change to an approved test procedure for active substance. Deletion of a non-significant specification parameter (deletion of an obsolete parameter) of a reagent used in the manufacturing of the active substance.
01 August 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
09 June 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
04 July 2023	Change in immediate packaging of the finished product.
05 April 2023	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier
03 February 2023	Changes to comply with Ph.Eur.
27 July 2020	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
30 July 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
11 June 2019	Changes to the quality control testing arrangements for the active substance –addition of a site where batch testing takes place.
10 May 2019	Change in distributor details from Vetoquinol UK Limited, Vétoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr. Alderton, Towcester, Northants, NN12 7LS
08 May 2015	Update to the DDPS.
11 November 2014	Change of distributor.
15 April 2014	Changes to an existing pharmacovigilance system.
23 December 2013	Renewal procedure – Ireland as RMS.
16 December 2013	To amend the shelf-life of the finished product from two years to three years.
12 September 2012	Change of distributor.
18 November 2011	To make changes to an existing pharmacovigilance system as described in the DDPS.
18 November 2011	To make changes to an existing pharmacovigilance system as described in the DDPS.
08 April 2010	To change the distributor from Pfizer Limited to Janssen Animal Health.
13 November 2009	To modify the syringe cap and plunger design.