Veterinary Medicines Directorate

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Post Authorisation Assessments

Antisedan 5 mg/ml Solution for Injection

Vm 06043/4004

•	08 November 2022	Minor changes to an approved test procedure for active substance.
•	27 January 2020	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	03 September 2019	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	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.
•	14 January 2019	Changes to the quality control testing arrangements for the active substance – addition of a site where testing takes place.
•	18 October 2018	Increase in the shelf-life of the finished product after first opening, from 28 days to 3 months.
•	03 July 2018	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.
•	10 July 2017	Minor changes to an approved test procedure of the finished product
•	08 December 2016	Change in the SPC, labelling or package leaflet due to new data.
•	10 November 2014	Change of distributor details.
•	10 March 2014	Change in the batch size of the finished product.
•	24 January 2014	Change to the primary packaging material not in contact with the product.
•	30 August 2013	Significant modifications to the SPC and product

		literature.
•	28 March 2012	Change of distributor details.
•	21 April 2010	Change of distributor.
•	23 February 2010	Change of MAH from Pfizer Limited to Orion Corporation and change of distributor.
•	08 January 2009	Renewal.
•	19 June 2008	Change in name and address of the manufacturer and assembler of the finished product.
•	21 November 2007	Updates to the package leaflet text.
•	28 June 2007	Changes to bring the SPC and product literature in line with new legislation and to change in legal category from POM to POM-V.
•	15 February 2007	Minor change in the manufacturing process of the active substance.
•	17 June 2005	Addition of a distributor.
•	04 April 2005	Renewal.
•	26 March 2004	Change in the name of an active substance manufacturer.
•	25 February 2004	Change in manufacturing process for the finished product and change in batch size.
•	30 April 2003	Renewal.
•	27 March 2003	Addition of indication for reversal of sedation with Dexdomitor.
•	05 February 2002	Change to the method for a test on the finished product.
•	23 February 2001	Change to the specification.
•	16 August 2000	Change of packaging component.
•	06 October 1998	Change to the specification.