Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Sedator 1.0 mg/ml Solution for Injection for Cats and Dogs

Vm 16849/4009

•	20 April 2023	Deletion of a non-significant specification parameter of an active substance.
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•	20 April 2023	Change in test procedure for the active substance. Change in the batch size range of the finished product. Change in the specification limits of the active substance. Introduction of a manufacturer of the active substance supported by an ASMF.
•	08 March 2022	Minor change to the restricted part of an Active Substance Master File. Tightening of specification limits of an intermediate used in the manufacturing process of the active substance.
•	08 April 2019	Changes to the labelling and package leaflet
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	01 June 2018	Change in RMS from UK to IE.
•	25 August 2017	Changes to the labelling and/or package leaflet.
•	16 December 2015	Variation to submit an updated version of the ASMF of the active substance.
•	19 April 2013	Change of QPPV and contact details for QPPV for an existing pharmacovigilance system.
•	04 March 2013	Widening of specification limits for a starting material that does not affect the overall quality of the active substance.
•	06 September 2012	Renewal
•	09 June 2011	Change in test procedure of the finished product.
•	23 February 2011	Change of Distributor.
•	31 March 2010	To change the user safety warnings.
•	17 October 2008	New MA (MRP)
•	04 May 2007	Change of distributor
•	25 April 2007	Change of Marketing Authorisation holder