

Post Authorisation Assessments

Vetergesic Multidose, 0.3mg/ml Solution for Injection for Dogs, Cats and Horses

Vm 15052/4081

•	14 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	16 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	18 December 2018	Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an finished product, packaging site, manufacturer responsible for batch release and site where batch control takes place. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	02 August 2018	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
•	23 August 2017	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.
•	15 March 2017	Change in storage conditions of the finished product or the diluted/reconstituted product deletion of 'Do not store above 25°C.'
•	16 December 2015	Changes to update the DDPS System.
•	22 June 2015	Change in legal entity.
•	15 April 2014	Introduction of a new pharmacovigilance system.
•	02 December 2014	Change in distributor details.
•	24 October 2014	Change to the name of the MAH, from 'Alstoe Limited' to 'Sogeval UK Limited'.
•	22 October 2014	Change to the text in section 4.11 of the SPC and product literature.
•	19 February 2014	Addition of a manufacturing site of the finished product.
•	14 January 2014	Submission of a new Ph. Eur. Certificate of Suitability for an active substance and change in

		specification parameter of the active substance.
•	11 December 2013	Renewal.
•	24 July 2012	Change of MA holder from Reckitt Benckiser
		Healthcare (UK) Limited to Alstoe Limited.
•	08 February 2012	Change in the specification/limits for the finished
		product.
•	27 October 2010	Replacement of a manufacturing site for part or all of
		the manufacturing process of the finished product.
•	09 September 2010	Extension to add indication for horses.