Veterinary Medicines Directorate

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Post Authorisation Assessments

Sedastart 1 mg/ml Solution for Injection for Cats and Dogs

Vm 19994/5009

•	29 October 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	20 July 2024	Deletion of a manufacturing site for an active substance (when mentioned in the dossier)
•	20 July 2024	Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a sterile or non-sterile finished product.
•	20 July 2024	Change in the specification parameters or limits of the finished product to describe more accurately the appearance of the product. Change in the specification parameters or limits of the finished product to describe more accurately the appearance of the product. Changes to the quality part of the dossier: Deletion of - a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) in the specification parameters or limits of the finished product. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) in the specification parameters or limits of the finished product. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) in the specification parameters or limits of the finished product.
•	20 July 2024	Replacement or addition of a secondary packaging site of a finished product.
•	20 July 2024	Change in test procedure for the finished product. Change in test procedure for the finished product. Minor change in the manufacturing process. Change in the specification parameters and/or limits

		of the finished product. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product. Change in type of container or addition of a new container.
•	06 July 2024	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	02 September 2019	Introduction of a new pharmacovigilance system.
•	26 May 2017	Tightening of in-process limits applied during the manufacture of the finished product
•	16 May 2017	Change in the batch size (including batch size range) of the finished product.
•	18 May 2016	Addition of a manufacturer of the active substance.
•	04 September 2015	Renewal.
•	07 October 2013	Change in distributor details.
•	27 April 2011	Submission of mock-ups.
•	18 April 2011	To change the distributor.
•	30 March 2011	Grouped variation to replace the manufacturing site where the finished product is manufactured, packed and analysed
•	29 December 2010	Change in the address of the Marketing Authorisation Holder.