Veterinary Medicines Directorate

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Post Authorisation Assessments

Sterilised Water for Injections BP

Vm 10434/4030

•	13 July 2023	Updated the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product.
•	15 June 2022	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Addition of a quality testing site for the finished product.
•	27 March 2020	Addition of a site where batch control/testing takes place.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	11 October 2017	Changes to the labelling and/or package leaflet.
•	29 September 2016	Change in the address of the Marketing Authorisation Holder.
•	14 October 2013	Variation to change the batch size of the finished product.
•	25 February 2013	Variation to change the supplier of a packaging component.
•	26 January 2011	Variation to change the address of a distributor.
•	15 January 2009	Renewal.
•	15 August 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	04 May 2007	Change of Marketing Authorisation Holder.
•	17 December 2004	Renewal.
•	17 November 1999	Renewal.
•	05 May 1998	Extension of shelf life.