



Post Authorisation Assessments

Librela 10 mg Solution for Injection for Dogs

Vm 42058/5030

• 26 May 2023	Extend the number of cycles of use for sepharose resin used in the downstream processing of bedinvetmab active substance.
• 23 March 2023	This variation was to add an alternate manufacturer of the active antibody component, namely Syngene International Limited.
• 24 January 2023	Addition of a secondary packaging site of a finished product. Addition of a secondary packaging site of a finished product.
• 07 December 2022	Change in the manufacturing process of the active substance.
• 13 April 2022	Changes to SPC and product literature following a PSUR.
• 19 January 2021	Increase in batch size of active substance or intermediate used in the manufacturing process of the active substance.
• 14 December 2021	Change of a test procedure for the active substance.