



Post Authorisation Assessments

Librela 20 mg Solution for Injection for Dogs Vm 42058/5032

12 May 2026	To increase the shelf life of the formulated drug substance (active substance) from 24 to 36 months.
14 January 2026	Addition of paresis, paralysis, seizure and immune-mediated polyarthritis to AE section. Update to special warnings section in SPC and QRD. Extension of the shelf life of the finished product to 36 months.
18 December 2025	To add an already authorised site for Physical/Chemical testing of the finished product to the manufacturing flow chart.
15 July 2025	Change in the specification parameters of a starting material.
07 January 2025	Change in role of a site involved in the manufacturing process of the active substance. Addition of a site where batch control/testing takes place.
03 December 2024	Adverse events sections updated following final PSUR requests after PSUR assessment.
13 June 2024	To remove a pH test following a modified method of production. To add an additional method comprising formulation in two tanks to one single low bioburden formulation/holding tank and add serial double filtration prior to filling.
18 May 2024	The scale for an immunological medicinal product is increased without process change. Addition of the manufacturer of a starting material used in the manufacturing process of the active substance.
27 February 2024	Approval of mock ups.
28 September 2023	To update the method used to produce and qualify future Librela Working Cell Banks.
19 September 2023	G.I.18 update to the national template. To process the changes following assessment of the PSUR (SPC, section 3.5 and 3.6. with corresponding sections of PL).s and the presentation of the adverse events within the table is in line with QRD template version 9.0.
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.