



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Cytopoint 30 mg/ml Solution for Injection for Dogs Vm 42058/5019

• 19 January 2023	Addition of a secondary packaging site.
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• 05 December 2022	Introduction of an alternative bioreactor for use during seed scale-up of the drug substance production process.
• 31 May 2022	Renewal.
• 14 January 2022	Replacement of a test procedure for the active substance. Replacement of a test procedure for the active substance. Replacement of a test procedure for the finished product.
• 22 September 2021	Minor change in the manufacturing process of the active substance.
• 27 August 2021	Change(s) in the SPC, Labelling or Package Leaflet products intended to implement the outcome of a procedure concerning PSUR
• 26 February 2021	Grouped variation for the deletion of a specification parameter used in the manufacturing process of the active substance and minor change in the manufacturing process of the active substance