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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

•	June 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