Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Cytopoint 40 mg/ml Solution for Injection for Dogs

Vm 42058/5020

31 January 2025	Deletion of the EU Local Representative addresses.
08 December 2023	Update to the GB national SPC QRD template.
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