



Post Authorisation Assessments

Pluset Powder and Solvent for Solution for Injection

Vm 20634/4000

23 March 2026	Addition of a site of manufacture for the finished product. One-off alignment of the product information with version 9.0 of the QRD template. Addition of a site of batch control for the finished product. Minor change in the manufacturing process of the finished product. Addition of a new batch size for the finished product.
20 June 2025	Change in batch size of finished product. Change to importer, batch release arrangements and quality control testing of the finished product. Addition of a manufacturing site for part or all of the manufacturing process of the finished product.
14 December 2024	Change in the batch size of the finished product.
13 April 2024	Change in the test procedure for identification and quantitative determination of the active substance. Change in the test procedure for identification and quantitative determination of the active substance. Change in the current method of determination the activity of FSH and LH in the finished product. (GB & NI)
31 January 2024	Change in address of sterility testing site. (NI)
05 December 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
15 August 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance. (GB)
08 August 2023	Addition of new distributor: Egg Technologies International Ltd, 18 Springfield Park, Tisbury, Salisbury, Wiltshire, SP3 6QN. United Kingdom.
14 July 2023	Change in address of sterility testing site.
26 October 2021	Deletion of a non-significant parameter of an active substance. Deletion of a non-significant parameter of an active substance. Replacement of a test procedure for the active substance. Replacement of a test procedure for the active substance.
21 October 2020	Replacement of a manufacturing site of the finished product.
12 November 2019	Change in the specification limits of the finished product.
19 September 2017	Change of manufacturing site for sterility testing. Change of manufacturing site for sterility testing.
04 August 2016	Harmonisation of the SPC and Product Information between the new and original member states, following a repeat use procedure.
24 October 2014	Change in the QPPV.
20 May 2011	Change to specification of the finished product.

	Change of batch size. Replacement of a manufacturer of an ingredient used in the manufacture of the finished product.
08 May 2009	Renewal.
09 July 2008	Updates to the SPC and Product Literature.
03 March 2008	Repeat use comm.