



Post Authorisation Assessments

Pluset Powder and Solvent for Solution for Injection Vm 20634/4000

•	15 August 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	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.