



Post Authorisation Assessments

Gletvax 6 Vm 60021/3077

01 April 2026	Add an already authorised site for biological testing of the active substance to the manufacturing flow chart. Add an already authorised site for Physical/Chemical testing of the finished product to the manufacturing flow chart.
22 May 2025	Change in legal entity of MA holder for UK(NI) to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland.
14 December 2024	4.5 Special precautions for use: Addition of "In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician". 4.6 Adverse reactions: Addition of "Hypersensitivity reactions may occur very rarely. Prompt subcutaneous administration of adrenaline may relieve the condition".
28 September 2022	Change in name and address of the manufacturer of the active substance.
19 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
07 November 2019	Replacement of a test procedure for the active substance.
19 June 2018	Changes to a test procedure for the active substance.
25 August 2016	Change to test procedures for the active substance. Change in the manufacturer of the active substance. Change in the manufacturing process of the active substance.
05 December 2014	Extension of the storage conditions of the active substance.
28 November 2014	Deletion of several non-significant in-process tests applied during the manufacture of the active substance.
25 June 2014	Increase in shelf life of the finished product from 18 months to 24 months.
04 December 2013	Change of a test procedure for the finished product.
04 December 2013	Change in legal entity from Pfizer to Zoetis. Change in distributor details from Pfizer to Zoetis. Change in name of a manufacturer of the active substance. Change in the name of a manufacturer of the finished

	product, also responsible for batch release.
08 November 2013	Widening of the in-process test limits applied during the manufacture of the active substance
17 October 2012	Change in a manufacturer or the active substance. Change in manufacture of a starting material used in the manufacturing process of the active.
11 July 2012	Change of manufacturing site for blending, filling and packaging, final product testing and batch release Minor changes to the manufacturing process of the finished product Addition of a new 100ml presentation Change in composition of the packaging Change of manufacturing site for manufacture/in-process control testing Change to specification of a starting material used in the production of the active substance
02 March 2011	Corrections to the specification of a starting material used in the production of the active substance
30 December 2010	Change of name of manufacture responsible for all parts of the manufacture of the finished product
06 September 2010	Renewal
01 July 2010	Addition of a manufacturing site for secondary packaging
29 June 2010	Addition of a manufacturing site for batch release
02 April 2009	Change of MAH and Distributor
16 April 2008	Addition of a manufacturing site of quality control testing
04 April 2007	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
28 October 2005	Change to test procedures performed on the finished product