Veterinary Medicines Directorate

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

Post Authorisation Assessments

Gletvax 6

Vm 42058/4070

•	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