



Post Authorisation Assessments

Framomycin 150 mg/ml Solution for Injection

•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	16 March 2016	Change in distributor details Change in legal entity
•	04 December 2014	Harmonisation of SPC and product literature with Ireland.
•	19 August 2014	Replacement of the site for EU market batch release.
•	08 March 2013	Submission of a new Ph. Eur. Certificate of Suitability for an active substance.
•	31 October 2012	Change of manufacturer of the dosage form. Change of assembler of the dosage form. Change of manufacturing site for batch testing.
•	28 October 2009	Renewal.
•	03 July 2008	Change of legal category from POM to POM-V. Changes to the SPC and Product Literature to bring in line with new legislation.
•	21 February 2008	Change of withdrawal period for Meat from Cattle from 49 days to 122 days, and for Milk from Cattle from 56 hours to 60 hours.
•	11 January 2008	Change of MAH and distributor address.
•	03 April 2001	Change of MAH.
•	14 January 2000	Renewal.