



Post Authorisation Assessments

Engemycin LA 200 mg/ml Solution for Injection Vm 01708/4338

•	24 August 2022	Change(s) in the SPC, labelling or package leaflet, to section 4.5, 4.6 and 4.8 of the Product information.
•	13 August 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	06 July 2020	Deletion of a pack size(s) of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Changes in the composition (excipients) of the finished product. Changes to the withdrawal period of the veterinary medicinal product. Change in the specification parameters of the finished product. Change in the specification parameters of the finished product.
•	03 July 2020	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	08 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	18 January 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	11 January 2016	Submission of a new or updated Ph. Eur. certificate of suitability.
•	25 October 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	06 December 2005	Renewal
•	12 May 2005	Change of distributor
•	14 January 2005	Addition of a manufacturer and assembler of the dosage form
•	03 December 2004	Change to a packaging component
•	23 May 2003	Renewal
•	22 May 2003	Change of withdrawal period for: Meat from Sheep from 21 days to 9 days Meat from Pigs from 14 days to 18 days

		Meat from Cattle from 28 days to 31 days Milk from Sheep from 8 days to 7 days Milk from Cattle from 7 days to 10 days
•	22 March 2002	Change of manufacturer of the active substance
•	27 July 2001	Addition of a distributor
•	02 June 2000	Change of address of the MAH
•	31 March 2000	Change of withdrawal period for Milk from Sheep to 8 days
•	16 June 1999	Addition of a non-food target species