



Post Authorisation Assessments

Mamyzin 269.5mg/ml Powder and Solvent for Suspension for Injection for Cattle

Vm 08327/5056

06 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
06 July 2022	Change in name of manufacturer of the active substance.
28 February 2022	Editorial change to excipient level.
12 November 2019	Changes to the labelling and/or package leaflet
31 July 2019	Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a secondary packaging site of the finished product. Addition of a secondary packaging site of the finished product. Decrease in batch size range of the finished product. Addition of a manufacturing site of the finished product. Addition of a manufacturing site of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
09 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
09 October 2017	Changes to the withdrawal period of the veterinary medicinal product. Change of the daily dose and treatment duration
20 August 2015	Change in name of manufacturer of the active substance.
25 June 2015	Change to the wording in Section 4.6 of the SPC.
10 June 2013	Change to name and address of a manufacturing site for the finished product
24 April 2012	Change of name of manufacturer for the finished product and batch release
17 February 2011	Deletion of a manufacturing site for the active substance, dosage form and assembler of the dosage form
17 March 2010	Minor changes to the SPC and Product Literature
08 April 2009	Change of withdrawal period for milk from cattle from 72 to 108 hrs

	Change of manufacturer of the active substance
09 April 2008	Addition of a manufacturer of the active substance
19 January 2007	Renewal
13 December 2006	Changes to the SPC and Product Literature to bring in line with new legislation
04 June 2004	Change of batch size Addition of a manufacturer of the dosage form
16 August 2002	Changes to the Product Literature to show the route of administration, and change the name of the diluent
08 March 2002	Change in manufacture of the dosage form
15 February 2002	Change to specification of the finished product Change to specification of the active substance
06 September 2001	Harmonisation of SPC
31 January 2001	Changes to the SPC
27 June 2000	Change of product name from 'Leocillin Injection' to 'Mamyzin'
12 April 2000	Change of MAH