Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 08327/4298

•	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