Veterinary Medicines Directorate

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Post Authorisation Assessments

Eprinex Pour-on for Beef and Dairy Cattle (Eprinomectin)

Vm 08327/4157

•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	03 November 2022	Addition of an alternate method (HPLC) to the current method (TLC) for In-Process control applied during the manufacture of the active substance.
•	01 August 2022	Deletion of a test procedure used in the manufacturing process of the active substance. Minor changes to an approved test procedure used in the manufacturing process of the active substance.
•	09 February 2022	Change in the name and address of a manufacturer used in the manufacture of the active substance.
•	28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	01 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	29 January 2018	Deletion of manufacturing site for an active substance.
•	23 March 2017	Change in the storage conditions of the finished product.
•	02 March 2017	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Changes to packaging manufacturers. Changes to the container/closure system.
•	02 March 2017	Addition of a new in-process test and limit applied during the manufacture of the active substance. Minor change in the manufacturing process of the active substance.
•	20 May 2015	Change of dosing device.
•	16 February 2015	Change in immediate packaging of the finished product.
•	13 May 2014	Replacement of a manufacturer of the active substance.
•	09 December 2013	Addition of a new manufacturing site for the active substance, changes to the manufacturing process of the active and changes to the test procedures for the active substance.
•	02 October 2013	Change of re-test period of an active substance.
•	07 May 2013	Deletion of a manufacturer of the active substance Deletion of a manufacturer of the finished product, packaging site and batch control site
•	03 October 2012	Change to specification of an active substance

•	07 December 2011	Change to test procedure performed on the active substance
•	18 April 2011	Addition of a manufacturer of a starting material used in the manufacture of an active substance
•	13 October 2010	Updates to sections 4.4 and 4.9 of SPC and Product Literature
•	19 May 2010	Change to test procedure performed on the active substance
•	13 January 2010	Changes to specification of the active substance Changes to test procedures performed on the active substance Addition of a site for manufacture, packaging and testing of the active substance Change to test procedure performed on the finished product Minor change in the manufacturing process of the active substance
•	01 August 2009	Change of name and address of a manufacturer of the active substance
•	24 March 2009	Change to a test procedure performed on the active substance
•	14 January 2008	Change to comply with an update of a monograph from a member state
•	11 October 2007	Removal of 2 test procedures performed on the active substance
•	04 October 2007	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
•	07 March 2007	Change of name of a site of manufacturing, packaging and testing
•	01 December 2006	Renewal
•	12 October 2005	Addition of 2 manufacturing sites
•	15 September 2005	Change of batch size
•	03 March 2004	Renewal
•	09 August 2002	Change of specification of the active substance
•	23 May 2000	Change of shelf life from 2 years to 3 years
•	28 September 1999	Change of withdrawal period
•	04 August 1999	Change to specification of the finished product
•	23 July 1998	Change of legal category to PML Change of MAH name and address
•	12 September 1997	Change of MAH
•	14 August 1997	Change to contraindications Change of withdrawal period