Veterinary Medicines Directorate

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Post Authorisation Assessments

Mastiplan LC, 300 mg/20 mg (Cefapirin/Prednisolone), Intramammary Suspension for Lactating Cows

Vm 01708/3010

•	20 October 2024	Introduction of a manufacturer of cefapirin sodium (active substance) supported by an ASMF.
•	11 June 2024	Addition of a bioburden test as an in-process control before irradiation during manufacture of the finished product.
•	14 July 2023	One-off alignment of the product information with version 9.0* of the QRD template.
•	17 January 2023	Change in the manufacturing process of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product.
•	28 September 2022	Extension of finished product shelf-life as packaged for sale.
•	03 March 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 August 2021	Replacement of a manufacturing site of the finished product.
•	12 March 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	January 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	10 August 2020	Change in the name of the manufacturer of the finished product.
•	02 March 2020	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Change in the address of a supplier of active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Tightening of an in-process limit applied during the manufacturer of the active substance. 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. Changes to a test procedure for the intermediate. Addition of an in-process test applied during the manufacture of the active substance. Minor change to the restricted part of an Active Substance Master File.
•	18 November 2019	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Changes to a test procedure for a reagent used in the manufacturing process of the active substance. Change in the name and address of a manufacturer of active substance used in the manufacture of the active substance. Change to an approved stability protocol. Tightening of specification limits of an active substance used in the manufacturing process of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Changes to a test procedure for the active substance.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	03 April 2017	Renewal – UK as CMS.
•	11 January 2017	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	22 June 2016	Removal of all national/country specific information from the foil sachet.
•	14 January 2016	Change of a measuring or administration device
•	01 July 2015	Harmonisation of the SPC and product literature.
•	25 March 2015	Repeat Use Comms.
•	26 November 2014	Update to the DDPS.
•	21 May 2013	Change in composition of outer packaging (resins change).
•	10 January 2013	Change in the site name of a manufacturer of the finished product.
•	15 November 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	15 November 2012	Submission of an updated Certificate of Suitability from an already approved manufacturer of an active substance leading to a deletion of a site of production and a change in the suppliers additional specifications.
•	25 October 2012	Renewal.
•	13 September 2011	To change the name of the active substance manufacturer.
•	18 April 2011	Update of a Ph. Eur Certificate of Suitability.
•	15 July 2010	Change in the specification parameters and or limits of the finished products.

•	05 June 2009	Change in batch size of finished product.
•	22 October 2008	Approval of new pack size for UK.
•	21 November 2007	Correction/simple text changes to SPC/ product literature.