



Post Authorisation Assessments

Mastiplan LC, 300 mg/20 mg (Cefapirin/Prednisolone), Intramammary Suspension for Lactating Cows Vm 01708/5077

• 14 July 2023	One-off alignment of the product information with version 9.0* of the QRD template.
• 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 manufacture 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

		<p>substance used in the manufacturing process of the active substance.</p> <p>Changes to a test procedure for a reagent used in the manufacturing process of the active substance.</p> <p>Change in the name and address of a manufacturer of active substance used in the manufacture of the active substance.</p> <p>Change to an approved stability protocol.</p> <p>Tightening of specification limits of an active substance used in the manufacturing process of the active substance.</p> <p>Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance.</p> <p>Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.</p> <p>Changes to a test procedure for the active substance.</p>
•	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.