Veterinary Medicines Directorate

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Post Authorisation Assessments

Prellim 0.075 mg/ml Solution for Injection for Cattle and Pigs

Vm 31592/5003

•	06 July 2024	Product literature harmonisation with the reference product.
•	09 November 2023	Change in the name of the active substance manufacturer, address remains unchanged.
•	21 April 2023	Change in name of manufacturer of finished product responsible for batch release. Change in MAH name and address from Laboratorios Syva S.A.U., Avda. Párroco Pablo Díez, 49-57, 24010 LEÓN, ESPAÑA to Laboratorios SYVA S.A., C/ Marqués de la Ensenada, 16, 28004 Madrid, Spain.
•	21 April 2023	Change in name of manufacturer of the finished product.
•	21 April 2023	One-off alignment of the product information with version 1 of the national QRD templates.
•	07 April 2022	Changes in the SPC, Labelling or Package Leaflet for harmonization of the SPC between original and new concerned Member States.
•	07 April 2022	Deletion of a pack size(s) of the finished product.
•	08 March 2022	Variation to update the Active Substance Master File.
•	13 October 2021	Increase in batch size (from 50 L batch size to batch range of 50 L - 157.5 L) of the finished product.
•	20 November 2020	Change in distributor details from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street London EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead Surrey KT22 7LP.
•	17 September 2019	Submission of an updated ASMF for an approved manufacturer of the active substance.
•	15 November 2018	Change in the number of units (e.g. tablets, ampoules, etc.) in a pack within the range of the currently approved pack sizes of the finished product.
•	10 April 2018	Repeat Use application to add 4 new member states
•	03 January 2018	Change to a test procedure for the finished product.
•	10 May 2017	Updates to the approved Active Substance Master File.
•	21 January 2016	Deletion of a manufacturing site.
•	06 October 2015	Addition of a specification test for the active substance. Addition of a new active substance manufacturer.
•	08 January 2015	Change to a limit test to comply with a Ph. Eur. monograph.
•	12 December 2014	Change in test procedure for the finished product.
•	23 April 2014	Renewal.

•	11 December 2013	Change of distributor.
•	28 August 2013	Change in the invented name of the product from ‘Luteosyl 0.075 mg/ml Solution for Injection’ to ‘Prellim 0.075 mg/ml Solution for Injection’.
•	26 August 2011	To change the manufacturer of the finished product responsible for batch release.
•	26 August 2011	To change the manufacturer of the finished product.
•	26 August 2011	To change the name of the MAH from from Laboratorios SYVA, S.A. to Laboratorios SYVA, S.A.U.