Veterinary Medicines Directorate

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Post Authorisation Assessments

Lutalyse 5 mg/ml Solution for Injection

Vm 42058/4082

•	15 September 2023	Addition of a test for microbial purity on the active substance specification.
•	15 September 2023	Submission of a new Ph. Eur. certificate of suitability for an addition of a new active substance manufacturer.
•	08 September 2023	Change in shape or dimensions of the container or closure:- Sterile medicinal product. Change in shape or dimensions of the container or closure:- Sterile medicinal products. Change in test procedure for the finished product: - Other changes to a test procedure. Change in test procedure for the finished product: - Other changes to a test procedure. Change in test procedure for the finished product: - Other changes to a test procedure. Change to importer, batch release arrangements and quality control testing of the finished product. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product: - Other changes.
•	05 July 2022	Change in shape of container for a sterile medicinal finished product.
•	07 April 2021	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	09 December 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	04 September 2020	Change in the address of the marketing authorisation holder 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.
•	15 November 2019	Change in shape or dimensions of the container or closure (immediate packaging). Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	15 November 2016	Deletion of a manufacturing site for an active substance.
•	12 May 2014	Change to importer, batch release arrangements and quality control testing of the finished product. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product. Change in the batch size (including batch size ranges) of

		the finished product. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	12 February 2014	Transfer of MA from Pfizer Ltd to Zoetis UK Limited and change of distributor.
•	29 January 2014	Changes to the specification parameters for the finished product.
•	18 April 2013	Updates to sections 4.2 and 4.9 of the SPC
•	04 September 2012	Change of specification of the active substance
•	10 June 2010	Renewal
•	11 November 2009	Change of withdrawal period for Meat from Cattle from 28 days to 1 day
•	13 August 2008	Changes to the SPC to bring in line with new legislation
•	06 June 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	20 March 2007	Change of MAH
•	26 July 2006	Addition of a parameter for a test performed on starting materials used in the production of the active substance
•	07 July 2005	Change of distributor
•	23 September 2004	Change to specification of the finished product
•	28 August 2003	Change of distributor
•	22 August 2001	Change of name of MAH