Veterinary Medicines Directorate

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Post Authorisation Assessments

Pathocef 250 mg Intramammary Suspension

Vm 42058/4094

•	13 January 2023	Deletion of a manufacturing site of the active substance.
•	05 May 2022	Submission of updated Ph.Eur. certificate of suitability for an active substance.
•	23 February 2022	Change in the manufacture of the finished product.
•	27 August 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.
•	22 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	29 March 2019	Minor changes to an approved test procedure of the finished product. Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product. Tightening of specification limits of the finished product.

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•	21 June 2017	Change in type of container for the finished product.
•	12 February 2014	Transfer of MA from Pfizer Ltd to Zoetis UK Limited and change of distributor.
•	26 April 2013	Variation to change the name and address of a Manufacturer.
•	16 January 2013	Minor change in the approved test procedure for the finished product.
•	22 December 2010	Change in the test procedure for the finished product.
•	25 August 2009	Variation to decrease the milk withdrawal period.
•	23 July 2009	Variation to change the name of the manufacturing site of the finished product.
•	16 January 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	09 August 2007	Variation to increase the milk withdrawal period.
•	09 August 2007	Renewal.
•	27 February 2003	Variation to change the name of the Assembler of Dosage Form.
•	12 January 2001	Renewal.
•	12 January 2001	Change to finished product formulation specification.