Veterinary Medicines Directorate

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Post Authorisation Assessments

Duphamox 150 mg/ml Suspension for Injection

Vm 42058/4043

•	08 April 2022	Change(s) in the SPC and Package Leaflet to implement the outcome of a procedure concerning PSUR.
•	25 November 2021	Deletion of a non-significant specification parameter of an excipient.
•	14 April 2021	Reduction of the shelf life of the finished product as packaged for sale from 2 years to 12 months.
•	26 August 2020	Change in the address of the MAH 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.
•	27 April 2020	Update of the test procedure to comply with the updated general Ph. Eur monograph. Update of the test procedure to comply with the updated general Ph. Eur monograph. Increase in batch size (including batch size range*) of the finished product. Increase in batch size (including batch size range*) of the finished product. Introduction of a new site of manufacture. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 October 2018	Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance.
•	04 May 2017	Changes to a test procedure for the finished product.
•	31 March 2015	Change to the name of an excipient, from 'Fractionated Coconut Oil' to 'Propylene Glycol Dicaprylocaprate'.
•	03 April 2014	Change of MAH from Pfizer Ltd to Zoetis UK Limited and change of distributor details.
•	02 May 2013	Change to container/closure system of the finished product
•	23 February 2010	Change of MAH
•	15 April 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in

		line with new legislation
•	14 June 2006	Addition of manufacturing sites for part of the manufacturing process of the active substance
•	30 March 2006	Renewal
•	23 May 2002	Change in manufacturing process of the active substance
•	07 November 2001	Renewal
•	01 November 2001	Change of withdrawal period
•	17 February 1998	Change of MAH
•	02 February 1998	Renewal