

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

## **Post Authorisation Assessments**

## Duphatrim IS Injectable Solution Trimethoprim 40mg and Sulfadiazine 200mg Solution for Injection

Vm 42058/4048

• 2	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.
•	13 March 2020	Minor changes to an approved test procedure of the finished product.  Deletion of a non-significant in-process test applied during the manufacture of the finished product.  Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.  Minor changes to an approved test procedure of the finished product.  Increase in batch size of the finished product.  Minor change in the manufacturing process of the finished product.
• (	09 March 2010	Change of MAH
• (	08 January 2009	Removal of a manufacturer of an active substance
•	12 December 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
• 2	26 October 2006	Renewal
• (	05 November 2004	Changes to SPC to bring in line with new legislation
• 1	11 July 2002	Renewal Change of manufacturing site of assembly
• 2	25 March 2002	Change of withdrawal period
• 1	17 February 1998	Change of MAH