



Post Authorisation Assessments

Medrone V Tablets 4 mg Vm 42058/4084

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| • | 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. |
| • | 04 September 2019 | Update of the quality dossier. |
| • | 02 July 2019 | Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Change in shape or dimensions of the container or closure. Change in immediate packaging of the finished product. |
| • | 02 August 2018 | Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 24 December 2015 | Approval of revised mock ups |
| • | 26 September 2013 | Change of MAH Change of distributor Change of name of manufacturer of the active substance Change of name of manufacturer of the finished product |
| • | 04 January 2011 | Submission of a new Ph. Eur. Certificate of Suitability for an active substance |
| • | 26 November 2010 | Change of address of a manufacturing site of the finished product |
| • | 08 March 2007 | Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation |
| • | 24 May 2006 | Renewal |
| • | 25 January 2006 | Change of manufacturer and assembler of the dosage form |
| • | 30 June 2005 | Change of distributor |
| • | 23 August 2004 | Change of MAH |
| • | 21 November 2003 | Renewal |
| • | 29 August 2003 | Addition of a distributor |
| • | 24 August 2001 | Change of name of MAH and address of manufacturer and assembler |
| • | 28 September 1999 | Change to name and address of the MAH |

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| • | 18 February 1998 | Change to manufacturer and assembler of the dosage form |
| • | 29 May 1997 | Renewal |