Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Cardisure Flavoured 1.25 mg Tablets for Dogs

Vm 16849/4026

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| • | 23 March 2022 | Minor change in the manufacturing process of the finished product. |
| • | 17 August 2021 | Increase in batch size (to 6.0 kg) of the active substance used in the manufacturing process of the active substance.<br>Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.<br>Change in the manufacture of the active substance.<br>Extension of a re-test period of the active substance. |
| • | 23 April 2020 | Changes to the labelling and package leaflet. |
| • | 31 December 2019 | Addition of a secondary packaging site of the finished product.<br>Addition of a primary packaging site of the finished product.<br>Addition of a manufacturing site of the finished product. |
| • | 24 January 2019 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 17 January 2019 | Addition of a manufacturer responsible for batch release including batch control/testing. |
| • | 30 August 2018 | Change in RMS from UK to NL. |
| • | 11 October 2016 | Change in product name in Norway only. |
| • | 12 July 2016 | Renewal – UK as RMS |
| • | 24 June 2015 | Change in name of supplier of a starting material.<br>Tightening of specification limits of the active substance.<br>Addition of a new specification parameter for the active substance. |
| • | 17 June 2015 | Changes to the labelling and package leaflet. |
| • | 07 August 2014 | To add an additional supplier of the starting material used in the manufacturing process of the active substance. |
| • | 13 May 2014 | Change of distributor and resulting change to mock-ups. |
| • | 13 February 2014 | Addition of a new manufacturing site responsible for the finished product, primary packaging, secondary packaging, batch control testing and batch release. |
| • | 24 October 2013 | Addition of a manufacturer for a starting material and changes in the manufacturing process of the active substance. |
| • | 11 July 2013 | Variation to correct the specification limits for protein of an excipient due to a typing error in original submission. |
| • | 25 March 2013 | Change of QPPV and contact details for the QPPV of an |

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| | | existing pharmacovigilance system. |
| • | 20 December 2012 | Minor change in the manufacturing process of the active substance. |
| • | 18 October 2012 | Minor change to an approved test procedure used in the manufacturing process of the active substance. |
| • | 04 April 2012 | Change in batch size of the active substance. |
| • | 04 August 2011 | Change to batch release arrangements and quality control testing of the finished product. |