Veterinary Medicines Directorate

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

Post Authorisation Assessments

Cardisure Flavoured 1.25 mg Tablets for Dogs

Vm 16849/3015

06 February 2026	Change in batch size of intermediate used in the manufacturing process of the active substance: up to 10-fold increase compared to the originally approved batch size. Change in batch size of intermediate used in the manufacturing process of the active substance: up to 10-fold increase compared to the originally approved batch size. Deletion of a non-significant specification parameter of an active substance. Deletion of a supplier of a starting material for an active substance. Minor change in the manufacturing process of an active substance. Change in the specification limits of a starting material used in the manufacturing process of the active substance.
06 January 2026	One-off alignment of the product information with version 9.1 of the QRD template.
19 December 2025	Minor change to the restricted part of an Active Substance Master File.
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. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Change in the manufacture of the active substance. 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. Addition of a primary packaging site of the finished product. 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. Tightening of specification limits of the active substance. 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 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.