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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Cerenia 16 mg Tablets for Dogs

Vm 42058/5009

26 March 2025	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State.
07 January 2025	Removal of the EU Local Representative Addresses from the GB texts.
24 December 2024	Extension of a re-test period/storage period supported by real time data.
14 December 2024	Changes in the manufacturing process of the active substance.
25 September 2024	Minor changes to the test method used to determine residual solvents in starting material (CP-123,328). Cp-123,328 is one of the starting materials used in synthesis of active substance Maropitant citrate. Through this variation correction factors have been used in the calculations for dichloromethane, toluene and tert-butylmethylether solvents. The data obtained by using correction factors are still well within the residual solvent specification of NMT 0.5%.
20 February 2024	One-off alignment of the product information with the latest QRD template.
19 January 2024	Minor change in the manufacturing process of the active substance.
03 November 2022	Change in name and address of a manufacturer of the active substance.
26 August 2022	Changes in the SPC, labelling or package leaflet to sections 4.6 and 6.
30 December 2021	To implement changes to the SPC and package leaflet following assessment of the PSUR.
16 November 2021	Change in the manufacturing process of the finished product.
08 April 2021	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.