



## Post Authorisation Assessments

For details of post authorisation assessments prior to 1<sup>st</sup> January 2021,  
please refer to the [EMA](#) website.

### Cerenia 10 mg/ml Solution for Injection for Dogs and Cats Vm 42058/5008

18 December 2025	Addition of a site where batch control or testing of the active substance takes place. Addition of a site where batch control or testing of the active substance takes place. Addition of a site where batch control or testing of the active substance takes place.
27 March 2025	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State.
12 March 2025	Deletion of a non-significant specification parameter of an active substance. Deletion of a non-significant specification parameter of an active substance.
13 January 2025	Removal of the EU Local Representative Addresses within 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%.
14 May 2024	Deletion of a non-significant specification parameter in the specification parameters of an excipient.
28 April 2024	Deletion of a manufacturing and primary packaging site of the finished product.
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.
28 April 2023	Deletion of a manufacturer of the finished product.
31 October 2022	Change in name and address of a manufacturer of the active substance.
02 September 2022	Change(s) in the SPC, labelling or package to section 4.6 and 6.
30 December 2021	To implement changes to the SPC and package leaflet following assessment of the PSUR.
16 December 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change to part of the (primary) packaging material not in contact with the finished product formulation.

08 April 2021

Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.