



Post Authorisation Assessments

Atipam 5.0 mg/ml Solution for Injection for Cats and Dogs Vm 16849/4011

18 February 2025	Alignment of the product information with version 9.0* of the QRD templates.
19 January 2022	Addition of a new specification parameter with its corresponding test method of an active substance. Addition of a new specification parameter with its corresponding test method of an active substance. Tightening of specification limits of an active substance. Minor change in the manufacturing process of the active substance. Extension of a re-test period of the active substance. Minor change to the restricted part of an Active Substance Master File.
20 December 2021	Increase in batch size (from 10 L - 100 L to 10 L - 250 L) of the finished product.
24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
30 August 2018	Change in RMS from UK to NL.
13 September 2017	Approval of mock ups
13 March 2015	Changes to the active substance master file.
05 June 2013	Renewal.
26 April 2013	Change of name and contact details of the QPPV.
16 February 2011	Change of Distributor.
21 August 2008	Variation to add three additional pack sizes of 4.8 kg, 6.4 kg and 8 kg.