Veterinary Medicines Directorate

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

Post Authorisation Assessments

Anesketin 100 mg/ml Solution for Injection for Dogs, Cats and Horses

Vm 16849/5002

•	10 November 2023	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. Addition of a new manufacturer of the active substance via submission of a Ph. Eur. CEP.
•	08 February 2023	Change(s) in the SPC, labelling or package leaflet to sections 4.5 & 4.6. One-off alignment of the product information with version 9.0 of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.
•	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.
•	05 June 2018	Renewal – UK as RMS
•	06 September 2017	Deletion of manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 May 2017	Changes to the labelling and/or package leaflet. Changes to the labelling and/or package leaflet.
•	05 August 2016	Change in distributor details.
•	19 August 2015	Changes to the labelling and package leaflet.
•	21 May 2014	Change in storage conditions of the finished product by the addition of ‘Keep the vial in the outer carton in order to protect from light’, minor editorial changes to the SPC and replacement of ‘detomidine’ in Section 4.9 of the SPC with ‘romifidine’.
•	07 October 2013	Approval of mock-ups for the 50 ml presentation.
•	26 April 2013	Change of QPPV name and contact details.