Veterinary Medicines Directorate

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Post Authorisation Assessments

Cevazuril 50 mg/ml, Oral Suspension for Piglets and Calves

Vm 15052/3040

22 December 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
20 October 2024	Change in the manufacturer of the active substance.
15 February 2024	Change in the manufacturing site of the active substance.
07 August 2023	Minor change in the manufacturing process of an aqueous oral suspension. Change in the holding time of an intermediate product. Change to in-process tests or limits applied during the manufacture of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product: - Other changes.
29 September 2022	Change of MAH address from: Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
29 December 2021	Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers. Change in the name of the manufacturer of the finished product. Deletion of a non-significant specification parameter of an excipient. Deletion of a non-significant specification parameter of an excipient. Deletion of a non-significant specification parameter of an excipient. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Addition of a site where batch control/testing takes place.
07 December 2021	Change to update an Active Substance Masterfile of a supplier.
07 December 2021	Change to update an Active Substance Masterfile of a supplier.
08 June 2018	To update QRD.
19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
16 February 2016	To change the re-test period of the active substance.. Minor change to the restricted part of an Active Substance Master File.
06 January 2016	Submission of a revised DDPS.

26 March 2015	Renewal – UK as CMS.
13 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
23 May 2014	Change in batch size of active substance used in manufacturing process. Deletion of a manufacturing site. Change in the specification limits of a reagent used in the manufacturing process of active substance. Changes to the manufacturing process of the active substance.
13 March 2014	Addition of cattle (calves) as a target species.
11 October 2013	Changes to an existing pharmacovigilance system.
27 March 2013	Addition of a new manufacturer of the active substance supported by an Active Substance Master File.
13 February 2012	To change the address of the UK Marketing Authorisation Holder.
06 January 2012	To change the name and address of the Marketing Authorisation Holder in Italy only.
27 May 2011	To change the colour of the polyproylene tamper-evident screw cap for the 1 litre presentation from green to white.
24 January 2011	To change the address of the Marketing Authorisation Holder in Denmark.
30 November 2010	Change in the specification parameters/and or limits of an excipient.
22 October 2010	To submit modified mock-ups in Spain and the UK prior to marketing the product.