



Post Authorisation Assessments

Cyclavance 100 mg/ml Oral Solution for Dogs and Cats Vm 05653/5045

•	20 September 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	03 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	25 January 2019	Renewal - UK as RMS.
•	08 January 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 October 2018	Change in RMS from UK to IE.
•	06 April 2018	Change in shape or dimensions of the container or closure (immediate packaging). Replacement of measuring device without CE markings which is not an integrated part of the primary packaging. Replacement of measuring device without CE markings which is not an integrated part of the primary packaging.
•	31 January 2018	Addition of a non-food producing target species.
•	15 September 2016	Change in distributor details.
•	28 July 2016	Change in shape or dimensions of the bromobutyl stopper.
•	10 July 2014	Addition of a new shape 5ml, 15ml, and 30 ml bottle. Addition of an aluminium flip-off cap and a new bromobutyl stopper for the new bottles. Addition of a 50 ml bottle with an aluminium flip-off cap and bromobutyl stopper. Addition of new 1 ml and 3 ml syringes. Addition of a polycarbonate dispenser cap with a silicone valve for the new shaped bottles.