



Post Authorisation Assessments

Libeo 40 mg Chewable Tablets for Dogs

Vm 15052/4105

•	30 July 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	17 July 2024	Change in immediate packaging of the finished product.
•	03 February 2023	Minor change to an approved test procedure for the active substance.
•	03 February 2023	Updated certificate of suitability from an already approved manufacturer.
•	13 December 2022	Updated certificate of suitability from an already approved manufacturer.
•	11 October 2022	Minor change to an approved test procedure for the active substance.
•	11 October 2022	Change in the address of the MAH 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.
•	23 November 2020	Deletion of manufacturing site for an active substance.
•	03 December 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	05 December 2018	Renewal – UK as CMS.
•	03 May 2018	Deletion of a manufacturing site for a packaging site and manufacturer responsible for batch release.
•	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.
•	12 July 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance
•	10 November 2016	Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product.

•	31 August 2016	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	16 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd.
•	18 November 2015	To increase the shelf life of Libeo 40 mg Chewable Tablets for Dogs from 2 years to 3 years
•	25 June 2015	Change of distributor. Changes to the product labelling.
•	10 July 2014	To change the shelf life of the finished product from 21 months to 2 years.