Veterinary Medicines Directorate

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Post Authorisation Assessments

Carprodyl Quadri 50 mg Tablets for Dogs

Vm 15052/5060

•	13 July 2023	Submission of a new Ph. Eur. CEP from a new manufacturer addition for a non-sterile: – active substance; – starting material.
•	30 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.
•	11 May 2022	Replacement to a test procedure for the finished product.
•	08 July 2021	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	19 December 2019	Update to the Active Substance Master File.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	22 January 2019	Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product.
•	26 September 2018	Replacement of a manufacturer responsible for batch release of the finished product. Deletion of a manufacturing site.
•	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 December 2016	Repeat Use - addition of Bulgaria, Cyprus, Czech Republic, Estonia, Ireland, Luxembourg, Poland, Portugal, Romania and Slovakia as

		CMS.
•	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.
•	20 October 2016	Change in the invented name of the medicinal product from "Dolagis 50 mg tablets for dogs" to "Carprodyl Quadri 50 mg tablets for dogs". Changes to the labelling which are not connected with the SPC.
•	25 August 2016	Approval of mock-ups for change of design/layout.
•	29 June 2016	Deletion of a manufacturer of the active substance.
•	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.
•	14 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd and Change of Distributor to Ceva Animal Health Ltd.
•	01 August 2012	Renewal procedure – France as RMS.
•	21 January 2011	Addition of a manufacturer of the active susbstance.
•	09 July 2010	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	09 July 2010	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	09 July 2010	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	28 April 2009	To extend the shelf life of the medicinal product.
•	26 January 2009	To extend the shelf life of the medicinal product.
•	06 June 2008	To add pack sizes.