

Post Authorisation Assessments

Filavac VHD K C+V Suspension for Injection for Rabbits Vm 46470/4000

•	30 October 2020	Renewal – UK as CMS.
•	January 2020	Change in the name of the product in Sweden from FILAVAC RHD Suspension for Injection for Rabbits to FILAVAC VHD K C+V Suspension for Injection for Rabbits.
•	24 October 2019	Change in the SPC, labelling or package leaflet due to new data.
•	24 October 2019	Change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product. Increase in the shelf-life of the finished product, from 14 months to 24 months. Deletion of a pharmaceutical form. Change in the fill weight/fill volume of the finished product.
•	01 October 2019	Change of a test procedure for the finished product.
•	01 October 2019	Change of a test procedure for the active substance.
•	09 July 2019	Change in storage conditions of the active substance.
•	26 November 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	11 July 2018	Change in distributor details. Addition of Ceva Animal Health Limited, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB.
•	28 February 2018	Repeat Use application to add 6 new member states.
•	08 September 2017	Change in the number of units (e.g. tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes of the finished product.
•	26 July 2017	Change in the address of the marketing authorisation holder from 20, La Corbiere 49450 Roussay, France to 20, La Corbiere-Roussay 49450 Sevremoine, France. Change in the address of a manufacturer of the finished product, also responsible for batch release.