



Post Authorisation Assessments

Floron 40 mg/g Oral Powder for Swine Vm 01656/5084

•	27 July 2021	Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place. Change in the name and address of a manufacturer used in the manufacture of the active substance.
•	19 November 2020	Update to ASMF.
•	21 June 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	15 January 2019	Minor change in the manufacturing process of the finished product.
•	18 December 2018	Extension of a re-test period of the active substance.
•	06 July 2018	Change in the RMS from UK to CZ.
•	03 July 2018	Addition of a site of manufacture.
•	13 March 2018	Changes to the quality control testing arrangements for the active substance - addition of a site where batch control takes place. Changes to the quality control testing arrangements for the active substance - addition of a site where batch control takes place.
•	20 February 2018	Renewal – UK as RMS.
•	15 July 2015	Approval of mock-ups.
•	02 June 2015	Addition of a local representative.