



Post Authorisation Assessments

Floron 40 mg/g Premix for Medicated Feeding Stuff for Pigs

Vm 01656/4011

16 May 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
22 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance. (GB).
15 October 2025	Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites). Deletion of a manufacturing site of the active substance.
01 May 2025	Alignment of the product information with version 9.0* of the QRD templates.
22 June 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
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.
02 July 2018	Addition of a manufacturer of the active substance or addition of a site of manufacture.
14 March 2018	Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place. Changes to the quality control testing arrangements for the active substance – addition of a site where batch control / testing takes place.
26 October 2017	Change in contact details for local representative.
06 July 2015	Renewal – UK as RMS.
29 May 2015	Addition of a local representative.
16 March 2015	Change of distributor.
24 October 2014	To change the date of submission of the PSUR.
11 September 2014	To extend the shelf life of the finished product, from 2 years to 4

	years.
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