Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Fenflor 300 mg/ml Solution for Injection for Pigs

Vm 01656/5065

30 June 2026	One-off alignment of the product information with version 3.0 of the QRD templates.
22 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
11 March 2025	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
10 November 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
21 March 2022	Change to the sterility test procedure for the finished product.
11 August 2021	Change in the name and address of a manufacturer of active substance used in the manufacture of the active substance. Changes to the quality control testing arrangements for the active substance – addition of a site where batch testing takes place.
12 April 2019	Tightening of specification limits of an active substance used in the manufacturing process. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.
08 March 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
28 January 2019	Extension of a re-test period of the active substance.
23 October 2018	Update to the Local Representative details.
17 April 2018	Change in RMS from UK to DE.
05 April 2018	Change to the quality control testing arrangements for the active substance - addition of a site where batch control takes place. Change to the quality control testing arrangements for the active substance - addition of a site where batch control takes place.
08 July 2015	Approval of mock-ups.
26 March 2015	Removal of distributor.
15 March 2013	Change to increase the shelf life of the finished product from 2 years to 3 years.
03 February 2012	To add a new supplier for rubber stopper.
03 September 2010	New MA – Extension to add a new route of administration (subcutaneous route).
02 June 2010	To add a distributor.
29 September 2009	New MA (MRP).
14 August 2007	Change of Marketing Authorisation Holder.