



Post Authorisation Assessments

Excenel 50 mg/ml Sterile Powder for Solution for Injection Vm 42058/4066

•	25 August 2023	Deletion of a manufacturing site for an active substance.
•	02 March 2023	Addition of a test procedure for the active substance. Addition of a new starting material manufacturer. Addition of a new active substance manufacturer.
•	28 August 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1 st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	07 February 2019	Changes in the manufacturers of the intermediate and final active substance.
•	07 September 2017	Deletion of a manufacturer responsible for batch release Deletion of manufacturing site where batch control takes place Deletion of manufacturing site for an intermediate Deletion of manufacturing site for an intermediate Deletion of manufacturing site for an intermediate
•	18 November 2015	Change in the name of manufacturer for the finished product.
•	20 October 2015	Change in name of manufacturer.
•	19 February 2015	Addition of an alternative site for batch control.
•	09 July 2013	Change of name and address of a manufacturer of the finished product and addition of a manufacturing site for batch release.
•	10 January 2013	Change of manufacturing process of the finished product. Addition of a new batch size. Change of specification limits for the finished product.
•	15 August 2012	Change of in use shelf life – addition of details after reconstitution. Addition of a 4g pack size. Updates to the SPC and Product Literature.
•	28 May 2012	Addition of a manufacturing site of batch release.
•	18 August 2010	Addition of a supplier of an intermediate used in the manufacture of the active substance.
•	08 July 2009	Addition of a new manufacturing site and site of assembly. Addition of an importer of the dosage form.

•	30 January 2008	Change of legal category from POM to POM-V. Changes to the SPC and Product Literature to bring in line with new legislation.
•	10 July 2006	Renewal.
•	09 December 2005	Change of name of manufacturing site of the finished product.
•	30 June 2005	Change of distributor.
•	23 August 2004	Change of MAH.
•	28 August 2003	Change of distributor.
•	03 May 2002	Addition of a manufacturer of the active substance.
•	22 August 2001	Change of name of MAH.
•	23 February 2001	Change of withdrawal period for meat from Pigs from 12 hours to 2 days. Deletion of chicks from the target species.