



Post Authorisation Assessments

Ivomec Premix for Pigs 0.6% Premix for Medicated Feed Vm 08327/4168

•	09 June 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	28 May 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	02 January 2019	Change in the manufacturing process of the active substance.
•	30 October 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	29 October 2015	Submission of an updated certificate of suitability for a manufacturer of an active substance.
•	20 October 2015	Submission of an updated certificate of suitability for a manufacturer of an active substance.
•	31 October 2012	Change of shelf life from 2 years to 3 years
•	26 June 2012	Submission of 2 updated Ph. Eur. Certificates of Suitability for an active substance Deletion of a manufacturing site of the active substance
•	24 February 2009	Change in test procedure performed on an excipient Change to comply with Ph. Eur. Replacement of manufacturing site for manufacture, packaging and testing, and batch release
•	28 January 2009	Change of batch release arrangements and quality control testing of the finished product Change to specification of an excipient
•	29 November 2007	Addition of 2 manufacturers of the active substance Submission of 2 New Ph. Eur. Certificates of Suitability for an active substance
•	01 November 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	13 September 2006	Renewal
•	15 November 2005	Change of shelf life from 1 year to 2 years Change of formulation of the product
•	25 October 2005	Change of withdrawal period for Meat from Pigs: For Pigs weighing less than 100kg from 7 days to 3 days For Pigs weighing more than 100kg from 28 days to 12 days
•	26 February 2003	Change of withdrawal period for Meat from Pigs from 7

		days to 7 days for Pigs weighing less than 100kg and 28 days for pigs weighing more than 100kg
•	13 December 2002	Renewal
•	07 May 1998	Change of name and address of MAH
•	24 December 1997	Renewal
•	16 October 1997	Change to specification of the active substance
•	10 October 1997	Change of type of non-sterile containers Changes to the shelf life
•	02 December 1996	Change to indications
•	26 September 1996	Updates to the SPC
•	24 August 1995	Change to dosage particulars