Veterinary Medicines Directorate

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Post Authorisation Assessments

Poulvac IBMM

•	18 November 2015	Change in name of manufacturer of the active substance. Change in name of manufacturer of the finished product.
•	20 October 2015	Change in name of manufacturer.
•	22 November 2013	Variation to monitor the active substance by testing the respective method recommended by the European Pharmacopoeia Monograph 5.2.2.
•	16 July 2013	Variation to replace test methods recommended in the European Pharmacopoeia Monograph 5.2.2.
•	13 June 2011	Addition of a supplier of starting material used in the manufacturing process.
•	18 January 2011	Variation to change the name of the site for batch release, importer of dosage form from outside EU, and the site for QC retesting if imported from outside EU.
•	23 November 2010	Variation to change the name of a manufacturing site.
•	16 June 2010	Variation to change the Marketing Authorisation Holder.
•	02 June 2010	Variation to replace the currently approved antibiotics.
•	08 October 2009	Renewal.
•	13 November 2008	Variation to update test methods (product).
•	15 July 2008	Alignment of the SPC and Product Literature between the UK and Ireland.
•	09 June 2006	Change to the currently approved extraneous agents testing of the finished product.