



Post Authorisation Assessments

Cyclix 250 microgram/ml Solution for injection for Cattle Vm 05653/5038

• 29 June 2020	Minor changes to an approved test procedure of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Changes to a test procedure for the finished product. Minor change in the manufacturing process. Qualitative and/ or quantitative changes to the excipients.
• 05 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
• 17 July 2015	Change in test procedure for the finished product. Change in the manufacturing process of the finished product. Change in the immediate packaging of the finished product.
• 15 April 2015	Change to section 4.6 of the SPC.
• 15 February 2015	Deletion of a manufacturing site of the finished product.
• 06 September 2012	To change the test procedure for the active substance to a BP method.
• 01 August 2012	To change the test procedure for the finished product.
• 4 July 2011	Renewal Marketing Authorisation.
• 6 November 2009	To add a production site of the finished product.
• 08 August 2008	To approve Virbac S.A. as an additional manufacturer of secondary packaging
• 08 August 2008	To approve Virbac S.A. as an additional site for batch release.
• 07 August 2008	To change the MAH from Intervet UK Ltd to Virbac S.A. and to change the distributor from Intervet UK Ltd to VIRBAC Limited
• 06 August 2008	To change the name of the manufacturer of the active substance.
• 13 February 2006	To add a new distributor for Northern Ireland.

