Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Cyclix 250 microgram/ml Solution for injection for Cattle

Vm 05653/5038

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| • | 29 June 2020 | Minor changes to an approved test procedure of the finished product.<br>Addition of a new specification parameter to the specification with its corresponding test method of the finished product.<br>Addition of a new specification parameter to the specification with its corresponding test method of the finished product.<br>Changes to a test procedure for the finished product.<br>Minor change in the manufacturing process.<br>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.<br>Change in the manufacturing process of the finished product.<br>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. |