



Post Authorisation Assessments

CIDR 1.38 g Vaginal Delivery System for Cattle Vm 42058/5114

•	25 January 2024	Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
•	10 November 2023	Updates in line with the latest version of the SPC/QRD.
•	24 November 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance.
•	30 October 2020	Changes to the labelling and/or package leaflet.
•	19 October 2020	Deletion of a test procedure for the finished product. Replacement to a test procedure for the finished product. Addition to a test procedure for the finished product.
•	06 August 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	17 January 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 November 2019	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 1st Floor, Birchwood Building Springfield Drive Leatherhead Surrey KT22 7LP.
•	09 August 2019	Change in the batch size of the finished product.
•	09 August 2019	Update to Section 4.5 (Special precautions for use) of the SPC and associated sections of the product literature, to include the phrase, 'Ensure correct administration; including use of a non-irritant antiseptic and lubrication (see section 4.9)', as requested during the recent PSUR procedure.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.

•	17 April 2018	Change in the RMS from UK to ES.
•	01 June 2017	Deletion of manufacturer responsible for batch release. Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	29 December 2016	Change in the address of the marketing authorisation holder in France, Czech Republic & Slovakia.
•	05 May 2015	Change in the QPPV contact details.
•	09 January 2014	Changes to the labelling to include a separate package leaflet.
•	11 October 2013	Change of MAH in Austria, Belgium, France and Luxembourg only.
•	10 October 2013	Addition of a finished product manufacturer and change to the QPPV details.
•	19 September 2013	Addition of new therapeutic indications.
•	16 August 2013	Change in distributor and MAH from Pfizer Limited to Zoetis UK Limited.
•	14 March 2013	Renewal procedure.
•	24 May 2012	Change of name of MAH in Spain only.
•	01 March 2012	To add a manufacturing site.
•	03 February 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	03 February 2012	To change the MAH in Poland only.
•	13 October 2011	Repeat Use procedure. UK as RMS.
•	26 February 2010	To update the European Pharmacopoeia Certificate of Suitability for Progesterone.
•	16 November 2009	To add an extraction efficiency correction factor to the calculation in the analytical method.
•	12 March 2009	Replacement of excipient with comparable excipient.
•	11 July 2008	New certificate of suitability for an active substance.