Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Ivertin 10mg/ml Solution for Injection for Cattle and Pigs

•	21 May 2019	Addition of a site where batch control/testing takes place. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Increase in batch size (including batch size range) of the finished product. Addition of a manufacturing site of the finished product.
•	25 April 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	22 June 2018	Renewal UK as CMS
•	06 July 2016	Change in the QPPV and/or QPPV contact details and/or back-up procedure which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	24 May 2016	Change of MAH from Laboratorios Calier, S.A. to Kela N.V.
•	10 July 2014	Changes to an existing pharmacovigilance system.
•	29 July 2013	Extension to add pigs as a target species.
•	11 June 2012	Change storage conditions to 'No special conditions of storage are required' and increase in shelf life to 36 months. Updated test methods and control of excipients and change in the composition of excipients. Changes to the tests on the finished product. An increase in batch size. Change in vial size with no effect on fill volume. Change to the specification parameters of the finished product and addition of a manufacturing site for the finished product. Deletion of 200 ml and 250 ml pack sizes.
•	14 December 2011	Deletion of an active substance manufacturer and submission of an updated Ph. Eur. Certificate of Suitability from an already approved manufacturer.
•	13 January 2011	Renewal.
•	19 October 2006	Addition of a secondary packaging site.
•	14 July 2006	Submission of a new Ph. Eur. Certificate of Suitability for a new active substance manufacturer.