Veterinary Medicines Directorate

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

Post Authorisation Assessments

ACEGON 50 micrograms/ml Solution for Injection for Cattle

Vm 31592/4005

•	03 May 2023	Changes in specifications of the active substance to comply with an updated monograph of the Ph. Eur. (NI)
•	15 March 2023	Change of the test procedure for the finished product. Change of the test procedure for the finished product Change of the test procedure for the finished product
•	17 February 2023	Change to in-process tests or limits applied during the manufacture of the finished product.
•	31 January 2023	Change of the test procedure for the finished product. Change of the test procedure for the finished product. Change of the test procedure for the finished product.
•	15 November 2022	Changes in specifications of the active substance to comply with an updated monograph of the Ph. Eur. (GB)
•	20 November 2020	Change in distributor details 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.
•	13 May 2020	Increase in batch size (from 100L to 100-157.5L) of the finished product.
•	27 November 2018	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.
•	28 August 2018	Deletion of a pack size of the finished product.
•	19 April 2018	Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.
•	07 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active from an already approved manufacturer.
•	13 July 2016	Renewal – UK as CMS
•	17 July 2014	Submission of a new Ph. Eur. Certificate of Suitability for the active substance.
•	02 July 2014	Changes to the therapeutic indications.
•	10 April 2014	Change in the invented name of the veterinary medicinal product in Italy only.
•	05 February 2014	Updated mock-ups approved.

•	23 October 2013	Repeat-Use procedure: UK comment.
•	22 July 2013	Change of distributor.
•	06 February 2013	Change of distributor.
•	02 January 2013	Change to the manufacturing process of the finished product.
•	27 August 2012	Deletion of a non-significant specification parameter from the Ph. Eur Certificate of Suitability.
•	27 August 2012	Submission of an updated Ph. Eur Certificate of Suitability for the active substance.