Veterinary Medicines Directorate

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

Post Authorisation Assessments

Allevinix 50 mg/ml Solution for Injection for Cattle, Pigs and Horses

Vm 15052/5042

•	12 March 2024	Change in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendations from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products. One-off alignment of the product information with version 9.0* of the QRD template.
•	26 September 2022	Change of MAH address from: Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	15 March 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	27 October 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	07 January 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	28 November 2019	Deletion of a pack size of the finished product. Deletion of a non-significant specification parameter of an excipient. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Replacement of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release including batch control/testing. Addition of new tests and limits applied during the manufacture of the finished product. Replacement of a secondary packaging site of the finished product. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.

		Change to in-process limits applied during the manufacture of the finished product. Changes in the composition (excipients) of the finished product. Replacement of a manufacturing site of the finished product.
•	30 April 2019	Introduction of a new pharmacovigilance system.
•	13 March 2018	Renewal - UK as CMS
•	13 June 2017	Change of MAH address from Merial Animal Health Limited to Ceva Animal Health Ltd. Change in distributor details from Merial Animal Health Limited to Ceva Animal Health Ltd.
•	28 March 2017	Addition of a manufacturer responsible for batch release of the finished product. Addition of a secondary packaging site of the finished product.
•	14 January 2016	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	15 December 2015	Changes to the SPC following a variation to the reference product. Change in the address of the manufacturing site. Replacement of a manufacturing site. Submission of an updated certificate of suitability. An Increase in batch size.
•	19 August 2015	Change of MAH, from Coophavet to Merial Animal Health Limited.
•	16 June 2014	Approval of product literature.
•	30 April 2014	Submission of an updated Ph. Eur. Certificate of Suitability from an already approved active substance manufacturer and submission of a new Ph. Eur. Certificate of Suitability from a new active substance manufacturer. Changes to the primary packaging not in contact with the finished product and change of specification parameters for the immediate packaging of the finished product.
•	14 April 2014	Change in distributor.
•	17 February 2014	Change in the invented name of the veterinary medicinal product. Addition of a manufacturer of the finished product.