Veterinary Medicines Directorate

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

Post Authorisation Assessments

Virbamec 1.0% w/v Solution for Injection for Cattle and Swine

Vm 05653/4204

13 July 2026	Change to comply with Ph. Eur.
03 October 2025	Change in shape or dimensions of the container: - Sterile medicinal products. Change in shape or dimensions of the container: - Sterile medicinal products. Change in shape or dimensions of the container: - Sterile medicinal products. Change in supplier of packaging components when mentioned in the dossier: - Other changes. Change in the specification parameters and/or limits of the immediate packaging of the finished product: - Other changes.
08 July 2025	Change in any part of the primary packaging material not in contact with the finished product formulation. Change in test procedure for the immediate packaging of the finished product: - including replacement.
11 April 2024	Change in shape or dimensions of the container or closure. Change in shape or dimensions of the container or closure. Change in shape or dimensions of the container or closure. Change in supplier of packaging components or devices.
16 October 2023	Deletion of one of the immediate packaging formulations of the finished product.
29 July 2020	Submission of a new certificate of suitability for an active substance.
26 May 2017	Minor changes to an approved test procedure of the finished product Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product Deletion of a non-significant in-process test applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product
09 December 2015	Change in legal entity of the MAH, from 'Virbac de Portugal Laboratórios Lda' to 'Virbac, France'.
15 June 2015	Submission of a new Ph. Eur. Certificate of Suitability.
23 May 2014	Deletion of a specification parameter for the finished product.
02 August 2011	Variation to change the batch size of the finished

	product.
02 August 2011	Addition of a manufacturing site for all of the manufacturing process, including batch release.
23 February 2011	Variation to change the name of the veterinary medicinal product.
12 January 2011	Variation to change the address of the Marketing Authorisation Holder.
24 November 2010	Variation to change the distributor.
04 December 2009	Renewal.
26 November 2009	Increase of a withdrawal period (cattle meat).
18 September 2008	Variation to change the name of the veterinary medicinal product.