Veterinary Medicines Directorate

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Post Authorisation Assessments

Virbamec Super 10 mg/ml, 100 mg/ml Solution for Injection

Vm 05653/4155

•	28 June 2024	Change of the porosity of the pre-filter in the manufacturing process of the finished product. Change of the specification limit for microbial contamination of Clorsulon.
•	28 June 2024	Change in the In-Process limit for the final solution before sterilising filtration.
•	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.
•	12 October 2023	Deletion of one of the immediate packaging formulations of the finished product.
•	23 June 2023	Deletion of a manufacturing site for the active substance.
•	20 December 2022	Introduction of a manufacturer of the active substance supported by an ASMF.
•	08 February 2022	Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	20 August 2020	Submission of a new certificate of suitability for an active substance.
•	15 August 2019	Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	17 June 2019	Change in the specification parameters and/or limits of an active substance.
•	31 January 2019	Addition of a manufacturer of the active substance.
•	24 October 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.
•	19 July 2017	Deletion of a manufacturing site for an active substance. Deletion of a manufacturing site for the finished product.
•	23 February 2017	Renewal.
•	14 May 2015	Change to the specification parameters of the finished product.

		Changes to the manufacturing processes of the finished product.
•	14 November 2014	Submission of a new Ph. Eur. Certificate of Suitability for a new active substance manufacturer. Change of distributor.
•	10 October 2014	Change in the invented name of the medicinal product, from 'Ivermectin and Clorsulon Solution for Injection for Cattle Virbac' to 'Virbamec Super 10 mg/ml, 100 mg/ml Solution for Injection'.
•	26 August 2014	Addition of a manufacturing site for the active substance. Change in the name of the manufacturing site.