Veterinary Medicines Directorate

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Post Authorisation Assessments

Ivermectin Virbac 10 mg/ml Solution for Injection

Vm 05653/4203

•	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.
•	13 October 2023	Deletion of one of the immediate packaging formulations of the finished product.
•	18 December 2020	Change in the invented name of the veterinary medicinal product from Premadex 1% w/v Solution for Injection for Cattle, Swine and Sheep to Ivermectin Virbac 10 mg/ml Solution for Injection. Change in distributor details from Downland Marketing Ltd, 15 Victoria Place, Carlisle, CA1 1EW to Virbac Ltd, Suffolk, IP30 9UP, UK.
•	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
•	9 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.
•	05 November 2012	Submission of an updated Certificate of Suitability for the Active Substance. Change in the retest period of the active substance.
•	12 January 2011	Variation to change the Marketing Authorisation Holder address.
•	11 August 2010	Variation to change the name of the veterinary medicinal product.
•	07 July 2010	Variation to change the distributor.
•	26 November 2009	Renewal.

•	28 January 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from PML to POM-VPS.
•	11 October 2007	Variation to change the batch size.
•	20 September 2007	Extension of the in-use shelf life.
•	09 May 2005	Replacement or addition of a manufacturing site for all or part of the manufacturing process of the finished product.
•	25 October 2006	Submission of a new Certificate of Suitability for the active substance.
•	01 May 2005	Extension of the finished product shelf-life.
•	30 December 2004	New Marketing Authorisation.