Veterinary Medicines Directorate

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Post Authorisation Assessments

IVERMECTIN AND CLORSULON 10 mg/ml / 100 mg/ml Solution for Injection for Cattle Virbac

Vm 05653/3028

•	19 October 2023	Changes to the quality part of the dossier: Deletion of - one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form.
•	12 January 2023	Introduction of a manufacturer of the active substance supported by an ASMF.
•	06 January 2022	Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	18 August 2020	Submission of a new certificate of suitability for an active substance.
•	22 October 2019	Change in the specification parameters and/or limits of an active substance
•	25 September 2019	Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	19 February 2019	Addition of a manufacturer of an active substance.
•	11 February 2019	Change in RMS from UK to IE.
•	04 July 2018	Change in the invented name of the veterinary medicinal product from Supremadex Solution for Injection to IVERMECTIN AND CLORSULON 10 mg/ml / 100 mg/ml solution for injection for cattle Virbac.
•	30 November 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.
•	14 August 2017	Deletion of manufacturing site for an active substance
•	09 December 2015	Change in legal entity of the MAH, from 'Virbac de Portugal Laboratórios Lda' to 'Virbac, France'.
•	14 May 2015	Change to the specifications of the finished product. Changes to the manufacturing processes of the finished product.
•	13 November 2014	Submission of a new Ph. Eur. Certificate of Suitability for an additional active substance manufacturer.
•	27 March 2014	Addition of a manufacturing site for an active substance.

•	22 February 2013	Variation to change the labelling on the finished product flasks.
•	18 May 2011	Grouped variation to submit an updated Certificate of Suitability from an already approved active substance manufacturer, and to change the name of the active substance manufacturer.
•	23 March 2011	Variation to seek approval for mock-ups prior to marketing.
•	18 February 2011	Variation to change the address of the Marketing Authorisation Holder. Deletion of an approved manufacturer of the finished product.
•	25 August 2010	Renewal. UK as RMS.
•	12 August 2009	Variation to change the name of the veterinary medicinal product.
•	22 July 2009	Variation to change the distributor.
•	08 January 2008	Batch size extension.
•	04 July 2007	Addition of a finished product manufacturer.
•	05 July 2006	Addition of an active substance manufacturer.
•	22 December 2005	Extension of the shelf-life of the finished product.
•	17 August 2005	New EUDE.