



## Post Authorisation Assessments

### Supremadex 10 mg/ml / 100 mg/ml Solution for Injection Vm 05653/5059

11 May 2026	One-off alignment of the product information with version 3 of the GB QRD templates.
18 September 2025	Change in dimensions of the immediate packaging. Change in dimensions of the immediate packaging. Change in dimensions of the immediate packaging. Change in supplier of packaging components. Change in specification parameters for the immediate packaging.
20 August 2025	Introduction of an additional new manufacturer of the active substance supported by ASMF.
14 July 2025	Change in a part of the primary packaging material not in contact with the finished product formulation. Test procedure for the immediate packaging updated.
08 April 2025	Submission of new mock ups.
10 July 2024	Change in the (invented) name of the veterinary medicinal product from Ivermectin and Clorsulon 10 mg/ml / 100 mg/ml Solution for Injection for Cattle Virbac to Supremadex 10 mg/ml / 100 mg/ml Solution for Injection.
18 May 2024	Change in the manufacturing process of the finished product. Change in the specification parameters and/or limits of an active substance.
18 May 2024	Tightening of in-process limits.
01 December 2023	Change in shape or dimensions of the container or closure - Sterile medicinal products. Change in shape or dimensions of the container or closure - Sterile medicinal products. Change in shape or dimensions of the container or closure - Sterile medicinal products. Change in supplier of packaging components or devices - Other changes
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.