



Post Authorisation Assessments

Release 300 mg/ml, Solution for Injection Vm 32829/5002

11 December 2024	One-off alignment of the product information with version 3 of the QRD template.
19 May 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance (used in manufacturing process of active).
30 October 2019	Increase in the shelf-life of the finished product after first opening, from 28 days to 63 days.
02 September 2019	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
27 February 2019	New certificate of suitability from a new manufacturer.
01 August 2018	Changes to the description of administration method.
30 August 2017	Change in the fill volume of the finished product.
03 August 2017	Changes to the labelling and/or package leaflet. Change in distributor details. From Chanelle Vet UK Ltd. to WDT-Wirtschaftsgenossenschaft deutscher Tierärzte eG.
25 May 2016	Addition of components (excipients) of the flavouring or colouring system of the finished product.
24 September 2014	To add wording to section 4.7 of the SPC.
02 June 2014	Changes to the SPC in line with similar products.
26 February 2014	Repeat Use – Comment.
30 July 2012	Submission of an updated certificate of suitability from an already approved manufacturer.
19 June 2012	Renewal procedure – Germany as RMS.
02 July 2009	Change of distributor of the Veterinary Medicinal Product.