Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Release 300 mg/ml, Solution for Injection

Vm 32829/5002

•	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.