

Post Authorisation Assessments

Quantilex Plus XL Tablets for Dogs Vm 08749/5052

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•	04 December 2023	One-off alignment of the product information with version 9.0 of the QRD template.
•	12 May 2023	Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	22 March 2023	Deletion of a manufacturing site for the active substance Febantel.
•	16 February 2023	Updated certificate of suitability from an already approved manufacturer.
•	16 February 2023	Updated certificate of suitability from an already approved manufacturer.
•	27 January 2023	Addition of a manufacturing site for the active substance.
•	13 April 2022	Update to ASMF.
•	20 January 2022	Deletion of manufacturing site for an active substance.
•	22 April 2021	Deletion of manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	05 November 2019	Increase in the shelf-life of the finished product as packaged for sale, from 3 years to 5 years.
•	15 July 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	13 February 2019	Update to the ASMF for an active substance.
•	10 January 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	15 May 2018	Renewal - UK as CMS
•	22 December 2017	Addition of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	29 January 2015	Repeat Use Procedure – Ireland as RMS.