



Post Authorisation Assessments

Quantilex Plus Tablets for Dogs Vm 08749/4054

•	31 January 2024	Added to SPC 4.6: In very rare cases slight and transient digestive tract disorders such as vomiting and /or diarrhoea may occur. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity.
•	13 December 2022	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	20 April 2022	Deletion of manufacturing site for an active substance. Deletion of Ph. Eur. certificates of suitability for an active substance. Deletion of Ph. Eur. certificates of suitability for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance.
•	12 December 2019	Increase in the shelf-life of the finished product as packaged for sale, from 3 years to 5 years.
•	20 August 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 March 2019	Change in RMS from UK to CZ.
•	13 February 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	12 July 2018	Update to the Active Substance Master File.
•	19 January 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	09 November 2017	Renewal – UK as RMS.
•	02 March 2017	Addition of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	26 November 2014	Introduction of a new DDPS.
•	06 November 2014	Change to the MAH.
•	27 October 2014	Submission of a new Ph. Eur. Certificate of Suitability. Deletion of a manufacturing site for an active ingredient.
•	05 June 2013	Introduction of a new manufacturer of the active substance.
•	24 January 2013	Submission of an updated certificate of suitability.

