



Post Authorisation Assessments

Prazitel Plus XL Tablets for Dogs

Vm 08749/3006

•	21 December 2023	Submission of an updated certificate of suitability.
•	08 June 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	12 May 2023	Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	22 March 2023	Submission of an updated certificate of suitability.
•	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.
•	11 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.
•	10 January 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	02 July 2018	ASMF updated.
•	22 December 2017	Addition of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	19 April 2017	Renewal – UK as CMS
•	26 October 2016	Change in the (invented) name of the veterinary medicinal product in Hungary.
•	15 May 2015	Submission of a new certificate of suitability.
•	06 November 2013	Submission of updated Ph. Eur certificates of suitability from already approved manufacturers of the active substances. Also a change in the invented name of the product in Belgium and Luxembourg only.
•	10 October 2013	Change in test procedure for the finished product.
•	1 May 2013	Approval of mock ups for the 50 pack size.