

Post Authorisation Assessments

Prazitel Plus Tablets for Dogs

Vm 08749/5055

31 July 2025	Addition of the following adverse events to section 4.6: Lethargy, anorexia, hyperactivity.
11 February 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
12 February 2024	Update to the latest version of the QRD
12 May 2023	Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
31 March 2023	Deletion of an active substance manufacturer.
16 February 2023	Updated certificate of suitability from an already approved manufacturer.
16 February 2023	Updated certificate of suitability from an already approved manufacturer.
24 January 2023	Addition of a manufacturing site for the active substance.
13 April 2022	Update to ASMF.
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.
10 October 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.
15 May 2015	Submission of a new certificate of suitability.
18 July 2014	Renewal procedure – Ireland as RMS.
10 June 2013	To add an additional active substance manufacturer.
01 February 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer.
02 May 2012	Submission of a new or updated Ph. Eur. Certificate of Suitability
02 July 2010	Variation to add a pork flavour to the tablets.

