Veterinary Medicines Directorate

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Post Authorisation Assessments

Cazitel Plus XL Tablets for Dogs

Vm 08749/5039

15 May 2026	Removal of one sentence in dosing instructions to aid in clarity plus addition of dosing table in Package leaflet.
31 July 2025	Addition of the following terms to section 4.6 adverse reactions: Lethargy, anorexia, hyperactivity.
01 December 2024	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.
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.
28 March 2023	Deletion of an active substance manufacturer.
17 January 2023	Additional manufacturing site for the active substance pryantel embonate.
23 September 2022	Updated certificate of suitability from an already approved manufacturer.
20 April 2022	Update to ASMF.
20 January 2022	Deletion of manufacturing site for an active substance.
06 May 2021	Change in distributor from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
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.
08 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.

13 April 2017	Renewal – UK as CMS.
15 May 2015	Submission of a new certificate of suitability.
12 November 2014	Change in distributor details.
01 October 2014	Change to the product name in Sweden only, from ‘Cazitel, 525 mg/504 mg/175 mg tablett för stora hundar’ to ‘Cazitel comp 525 mg/504 mg/175 mg tabletter för stora hundar’.
17 October 2013	Submission of updated Ph. Eur. Certificates of Suitability.
07 October 2013	Change in test procedure for the finished product.
13 June 2013	Updates to product literature.
15 May 2013	Change of distributor.