

Post Authorisation Assessments

ITCH WORMER Plus XL Tablets for Dogs

Vm 40162/4017

12 January 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
12 January 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
19 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 July 2022	Updated certificate of suitability from an already approved manufacturer.
07 June 2022	Deletion of a manufacturing site for an active substance.
07 June 2022	Deletion of a certificate of suitability for an active substance.
01 June 2022	Deletion of a certificate of suitability for an active substance.
01 June 2022	New certificate of suitability for an active substance from a new manufacturer.
01 June 2022	Deletion of a certificate of suitability for an active substance.
01 June 2022	Updated certificate of suitability for an active substance from an already approved manufacturer.
13 May 2022	Changes to the labelling and/or package leaflet.
15 June 2021	Renewal – UK as CMS.
September 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
30 May 2019	Change in the invented name of the veterinary medicinal product from Extrontel Plus XL Tablets for Dogs to ITCH WORMER Plus XL Tablets for Dogs
29 November 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
17 August 2018	Updates to the SPC following a periodic safety update report.
24 July 2018	Update to the active substance master file.
04 January 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance.
04 September 2017	Change of legal distribution category from NFA-VPS to AVM-GSL and associated changes to the SPC and product literature.
22 June 2016	Increase in the shelf-life of the finished product as packaged for sale, from 3 years to 5 years.
14 June 2016	Submission of a new certificate of suitability.