



Post Authorisation Assessments

ITCH WORMER Plus XL Tablets for Dogs

Vm 40162/4017

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| • | 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. |