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Post Authorisation Assessments

Mektix Chewable 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg

Vm 01656/3052

• 14 May 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
• 03 May 2024	Repeat use to add one CMS.
• 03 May 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.
06 March 2024	Submission of a new Ph. Eur. certificate of suitability for a manufacturer of the active substance.
• 09 August 2023	Alignment of the product information with version 9.0* of the QRD template
• 08 August 2023	Addition of a manufacturer responsible for batch release including batch control.
• 24 January 2023	Change in product name from Mektix Chewable 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg to Mektix vet 16 mg/40 mg film-coated tablets for cats weighing at least 2 kg in DK only.
• 13 December 202	Additional site of batch release & QC testing.
• 08 March 2022	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 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. Submission of a new Ph. Eur. certificate of suitability for an active substance.
• 27 January 2022	Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product. Addition of a manufacturing site of the finished product.
• 30 July 2021	Update of the adverse reactions information for the Summary of Product Characteristics and product literature.
• 14 October 2019	Change in the invented name of the veterinary medicinal product from Mektix 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg to Mektix Chewable 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg
10 September 20	19 Change to an in-process test applied during the manufacture of the finished product.

Changes of components (excipients) of the flavouring or colouring system of the finished product. Changes in components (excipients) of the flavouring or colouring system of the finished product. Changes to a test procedure for the finished product.
Changes to a test procedure for the finished product. Replacement of an excipient with a comparable excipient.