Veterinary Medicines Directorate

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Post Authorisation Assessments

Exitel 230/20 mg Flavoured Film-coated Tablets for Cats

Vm 08749/5041

•	11 May 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	21 July 2023	Change(s) in the SPC, labelling or package leaflet to sections Adverse events: in very rare cases, gastrointestinal disorders such as hypersalivation and /or vomiting & neurological signs such as ataxia and muscle tremors have been observed.
•	21 July 2023	One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004
•	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.
•	14 July 2021	Change in the invented name of the veterinary medicinal product from Exitel 230/20 mg flavoured film coated tablet for cat to Cat-Ex 230/20 mg flavoured film coated tablet for cat in Spain (ES) only.
•	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.
•	16 October 2019	Increase in the shelf-life of the finished product as packaged for sale, from 4 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.
•	27 November 2018	Renewal – UK as CMS
•	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.

•	19 November 2014	Repeat Use procedure.
•	07 March 2014	Change in the invented name of the veterinary medicinal product.