

Post Authorisation Assessments

Exitel 230/20 mg Flavoured Film-coated Tablets for Cats Vm 08749/5041

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•	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
•	17 January 2025	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
	40.0-1-1-2010	an active substance from a new manufacturer.
•	16 October 2019	Increase in the shelf-life of the finished product as
	15 July 2010	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
•	27 November 2018	approved manufacturer. 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
•		Change in the invented name of the veterinary medicinal

product.
