Veterinary Medicines Directorate

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Post Authorisation Assessments

Kelapril 5 mg, Film-coated Tablets for Dogs and Cats

Vm 57446/3003

•	27 March 2024	Changes to the quality part of the dossier: Deletion of a manufacturing site for finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place.
•	02 January 2024	Alignment with version 9 of the QRD templates.
•	23 January 2023	Change in MAH from Richter Pharma AG, Feldgasse 19, 4600 Wels, Austria to VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria
•	28 September 2022	Addition of an alternative composition of immediate packaging for the finished product. Addition of a batch control testing site for the finished product. Deletion of an obsolete tests during manufacture of the finished product. Deletion of an obsolete parameter in the specification for the finished product. Addition of a manufacturer responsible for primary packaging of the finished product. Addition of a manufacturer responsible for secondary packaging of the finished product.
•	26 September 2022	Minor changes to the manufacturing process of the finished product.
•	26 July 2022	Addition of manufacturing site for the manufacture of the finished product.
•	23 July 2021	Change in distributor details from Anglian Nutrition Products Company (ANUPCO), Crockatt Road, Lady Lane Industrial Estate, Hadleigh, Ipswich, Suffolk IP7 6RD UK, to ANUPCO Limited, Office 39, Lodge Park, Lodge Lane, Langham, Colchester, Essex CO4 5NE, England.
•	28 May 2021	Minor changes to an approved test procedure of the finished product.
•	25 November 2020	Change in the specification limits of the finished product.
•	31 January 2020	Change in the invented name of the veterinary medicinal product from Kelapril 5 mg Film-Coated Tablets for Dogs and Cats to Benadil 5 mg Film-Coated Tablets for Dogs and Cats in the Czech Republic, Belgium, Germany, Hungary, Luxembourg, Poland, Portugal, Slovakia, and the Netherlands.
•	13 January 2020	Introduction of a new pharmacovigilance system.
•	30 December 2019	Replacement of a manufacturer responsible for batch release of the finished product.

•	30 December 2019	Addition of a secondary packaging site of the finished product.
•	10 October 2019	Change of MAH, from Kela N.V. to Richter Pharma AG.
•	25 April 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	07 August 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	21 December 2017	Renewal UK as CMS
•	22 June 2017	Reduction of the shelf life of the finished product as packaged for sale from 30 months to 24 months. Change in storage conditions of the finished product. Change in the specification parameters of the finished product.
•	13 September 2016	Change in distributor details.
•	24 September 2015	Submission of a new certificate of suitability from a new manufacturer.
•	03 October 2014	Change to distributor address.
•	15 April 2014	Change in distributor.
•	03 May 2013	Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product.