Veterinary Medicines Directorate

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Post Authorisation Assessments

Zipyran Tablets for Dogs

Vm 20634/4004

•	28 April 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (NI) Changes to the quality part of the dossier: Deletion of - a Ph. Eur. CEP for an active substance. (NI)
•	28 April 2024	Changes to the quality part of the dossier: Deletion of - a Ph. Eur. CEP for an active substance. (GB) Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (GB)
•	15 August 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	11 September 2020	Submission of a new 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
•	10 July 2018	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Addition of a manufacturer of the active substance or addition of a site of manufacture.
•	18 May 2017	To update the SPC and Product Literature in line with the outcome of a renewal procedure.
•	13 January 2017	Submission of an updated Ph. Eur. certificate of suitability.
•	22 December 2016	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	08 September 2016	Renewal – UK as CMS
•	05 August 2015	Change in the batch size of the finished product. Replacement of the primary packaging site of the finished product. Replacement of a manufacturing site for all of the manufacturing process of the finished product.
•	30 July 2015	Submission of a new certificate of suitability from a new manufacturer, and a replacement of a certificate of suitability.

•	20 March 2015	Addition of a secondary packaging site and a batch release site (for The Netherlands only). Addition of a pack size for the finished product.
•	03 April 2013	Added the wording ‘Beef Flavoured’ to the packaging.
•	03 April 2013	Change in the name of the product from ‘Zipyran Plus Tablets for Dogs’ to ‘Zipyran Tablets for Dogs’
•	03 April 2013	Submission of a new Ph. Eur. Certificate of suitability for an active substance from a new manufacturer.
•	21 December 2012	To change the flavouring component.
•	13 October 2011	To change the components of the flavouring system.