



Post Authorisation Assessments

Zipyran XL Tablets for Dogs

Vm 20634/4008

•	13 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
•	19 February 2019	Increase in the shelf-life of the finished product as packaged for sale, from 30 Months to 36 Months.
•	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.
•	19 July 2016	Renewal – UK as CMS
•	10 August 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).