



Post Authorisation Assessments

Therios 75 mg Chewable Tablets for Cats Vm 15052/4118

•	06 October 2022	Change in the MAH address, from Ceva Animal Health Ltd, Unit 3, Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Ceva Animal Health Ltd, Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	01 July 2020	Deletion of a non-significant specification parameter of an excipient.
•	17 February 2020	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.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	26 September 2018	Replacement of a manufacturer responsible for batch release of the finished product. Deletion of manufacturing site.
•	23 March 2018	Change in the invented name of the veterinary medicinal product in DK and NO: From: Therios 75 mg Chewable Tablets for Cats To: Therios vet 75 mg Chewable Tablets for Cats
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	10 November 2016	Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product.
•	16 August 2016	Changes to the date of the audit to verify GMP compliance of the manufacturer of the active substance.
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	16 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd.

•	07 October 2015	Change in distributor and approval of mock-ups.
•	28 July 2015	Submission of and updated certificate of suitability, and a deletion of a manufacturing site for the active substance.
•	15 July 2015	Renewal procedure – France as RMS.
•	11 May 2012	Change in shelf life of the polyvinylchloride/ thermo-elast/ polyvinylchloride – aluminium heat sealed blister from 24 to 36 months.
•	06 September 2011	Repeat Use Procedure
•	20 December 2010	Change in shelf-life from 18 to 24 months.