Veterinary Medicines Directorate

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Post Authorisation Assessments

Zodon 25 mg/ml Oral Solution for Cats and Dogs

Vm 15052/4125

•	19 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
•	04 February 2022	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 August 2020	Deletion of an immediate packaging container Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product Addition of a new specification parameter to the specification with its corresponding test method of the immediate packaging of the finished product Deletion of a non-significant specification parameter of the immediate packaging of the finished product Deletion of a non-significant specification parameter of the immediate packaging of the finished product Deletion of a non-significant specification parameter of the immediate packaging of the finished product
•	30 August 2019	Increase in batch size of the finished product. Increase in batch size of the finished product. Increase in batch size of the finished product. Increase in batch size of the finished product. Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release of the finished product. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product. Change in shape or dimensions of the container or closure (immediate packaging). Change in shape or dimensions of the container or closure (immediate packaging). Change in shape or dimensions of the container or closure (immediate packaging). Addition of a manufacturing site of the finished product.

		Change in test procedure for an excipient.
•	23 July 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	07 March 2019	Renewal – UK as CMS
•	18 October 2018	Replacement of a manufacturer responsible batch release of the finished product.
•	22 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 May 2018	Change in the invented name of the veterinary medicinal product in Denmark, Finland, Norway, Luxembourg and the Netherlands.
•	21 February 2018	Repeat Use application to add 7 new member states
•	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.
•	29 August 2017	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
•	09 November 2016	Change in the name of the manufacturer of the finished product including manufacturer responsible for batch release.
•	16 August 2016	Increase in the shelf-life of the finished product as packaged for sale, from 21 months to 3 years.
•	03 August 2016	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	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.
•	02 October 2014	Approval of joint-labelling for mock-ups. Change to the distributor details in the UK only.
•	28 May 2014	Extension of shelf life of the product as packaged for sale from 15 months to 21 months.