Veterinary Medicines Directorate

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Post Authorisation Assessments

Zelys 10 mg Chewable Tablets for Dogs

Vm 15052/5053

•	21 November 2023	Tightening the specification limit for the test of loss on drying. Tightening the specification limit for the test of assay. Tightening the specification limit for the test of related substances.
•	07 November 2023	Submission of an updated CEP for pimobendan for veterinary use.
•	11 May 2023	Increase in the shelf life of the finished product in blister presentation from 2 years to 3 years.
•	14 March 2022	Change in the specification limits of the immediate packaging of the finished product.
•	21 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 August 2022	Unlimited renewal.
•	27 May 2021	Increase in the shelf-life of the finished product as packaged for sale, from 18 months to 2 years.
•	11 May 2021	Change in the invented names of the veterinary medicinal products from Zelys Vet 1.25 mg Chewable Tablets for Dogs, Zelys Vet 5 mg Chewable Tablets for Dogs and Zelys Vet 10 mg Chewable Tablets for Dogs to Zelys 1.25 mg Chewable Tablets for Dogs, Zelys 5 mg Chewable Tablets for Dogs and Zelys 10 mg Chewable Tablets for Dogs in DK, FI, NO, and SE.
•	28 April 2021	Deletion of a therapeutic indication.
•	31 March 2021	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance.
•	21 May 2020	Addition of a new container for the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form. Change in the specification of the finished product to update appearance (single scored). Changes in scoring/break lines intended to divide into equal doses. Minor adjustments of the quantitative composition of the finished product with respect to excipients. Minor adjustments of the quantitative composition of the

		finished product with respect to excipients. Change in the SPC, labelling or package leaflet due to new data.
•	11 February 2020	Deletion of a non-significant specification parameter of the finished product. Widening of the in-process limits applied during the manufacture of the finished product. Widening of the in-process limits applied during the manufacture of the finished product.
•	01 August 2019	Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer.
•	23 May 2019	Replacement of a site where batch control/testing takes place