Veterinary Medicines Directorate

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Post Authorisation Assessments

Enurace 10, 10 mg Tablets for Dogs

Vm 32742/4001

•	20 December 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
•	08 April 2020	Change in the batch size (260,000 to 520,00 tablets (91 to 182 kg)) of the finished product. Minor change in the manufacturing process of the finished product.
•	28 June 2019	Change in shape or dimensions of the container or closure (immediate packaging). Change in type of container for the finished product.
•	06 November 2018	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 January 2017	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 November 2012	Addition of secondary packaging site of the finished product
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•	23 April 2012	Renewal procedure – The Netherlands as RMS.
•	21 March 2012	To change the distributor.
•	10 November 2011	To change the name of the active substance manufacturer.
•	31 October 2011	To update the pharmacovigilance system.
•	15 February 2011	Change to batch release arrangements and quality control testing of the finished product.
•	9 February 2011	Change of Marketing Authorisation Holder from Ecuphar Veterinary Products BV to Ecuphar NV.