Veterinary Medicines Directorate

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Post Authorisation Assessments

Enurace 10, 10 mg Tablets for Dogs

Vm 32742/4001

03 November 2026	Submission of an updated Ph. Eur. CEP for a non-sterile active substance – the remaining API manufacturer remains unchanged; however, the name, address and CEP version have been updated. Replacement of a secondary packaging site of a non-sterile finished product. Replacement of a primary packaging site of a non-sterile finished product. Replacement of a manufacturing site responsible for batch release of a non-sterile finished product. Deletion of a manufacturing site for an active substance.
03 November 2026	Replacement of a manufacturing site for part or all of the manufacturing process of the finished product. Alignment of the product information with EU version 9.1 and GB v3 of the QRD templates. Change to in-process tests or limits applied during the manufacture of the finished product. Change in the specification limits of the finished product - Change outside the approved specifications limits range. Minor change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product.
22 June 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
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.