Veterinary Medicines Directorate

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Post Authorisation Assessments

Enurace 50, 50 mg Tablets for Dogs

Vm 32742/4002

•	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)
•	10 November 2020	Change(s) in the SPC, Labelling or Package Leaflet of veterinary medicinal product intended to implement the outcome of a procedure concerning PSUR.
•	08 April 2020	Change in the batch size (380,000 to 760,000 tablets (95 - 190 kg)) of the finished product. Minor change in the manufacturing process of the finished product.
•	28 June 2018	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 November2012	Addition of secondary packaging site of the finished product
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•	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.
•	18 October 2011	Renewal procedure – The Netherlands as RMS.
•	15 February 2011	Change to batch release arrangements and quality control testing of the finished product.
•	09 February 2011	To change the MAH from Ecuphar Veterinary Products BV to Ecuphar NV.
•	03 November 2009	To submit a new Ph. Eur certificate of suitability for Ephedrine HCI
•	30 April 2009	To change the name and address of the Marketing Authorisation Holder.
•	30 October 2008	To update part 2 of the dossier
•	30 October 2008	Addition of a second AIM.