Veterinary Medicines Directorate

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Post Authorisation Assessments

Torbugesic 10 mg/ml Solution for Injection

Vm 60021/3023

•	15 November 2024	Change of Legal Entity for UK(NI) from Zoetis UK Limited to Zoetis Belgium S.A.
•	21 October 2024	Minor update to the test procedure for detection of degradation products in the finished product. Minor update to the test procedure for identification and assay of butorphanol tartrate.
•	25 June 2024	Change in any part of the primary packaging material not in contact with the finished product formulation.
•	20 May 2021	Update of ASMF.
•	06 November 2020	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	06 January 2019	Minor change in the manufacturing process of an immediate release solid oral dosage form. Change in the release and shelf-life specifications of the finished product.
•	10 February 2015	Harmonisation procedure with Ireland.
•	23 December 2013	Grouped variation to transfer the Marketing Authorisation Holder (including a change in distributor), to change the name of the finished product manufacturer (responsible for batch release), and to amend the strength of the product in the product name.
•	28 June 2011	Variation to change the name of the manufacturer/assembler for finished product.
•	26 January 2011	Variation to update the Part II of the dossier and subsequently change the manufacturer and assembler of dosage form.
•	24 June 2010	Variation to change the name and address of a manufacturer of the finished product.
•	16 June 2010	Variation to change the Marketing Authorisation Holder (and subsequently the distributor).
•	03 February 2010	Variation to decrease the horse withdrawal period.
•	11 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	31 January 2006	Renewal.
•	22 April 2004	Change of importer.
•	10 July 2002	Variation to change the active substance manufacturer.
•	20 May 2002	Renewal.

•	21 November 2001	Variation to remove the horse withdrawal period.
•	13 November 2001	Variation concerning an active substance manufacturer.
•	06 January 2000	Variation to change the dosage form manufacturer.
•	23 August 1999	Variation to increase the batch production size.
•	27 March 1998	Change in the clinical particulars.
•	24 March 1998	Variation to change the importer of the final dosage form.
•	24 March 1998	Variation to update licence particulars.
•	31 July 1997	Renewal.
•	07 November 1996	Variation to change the address of the ATC/PL Holder.
•	24 January 1995	Variation to update the dosage particulars.