Veterinary Medicines Directorate

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Post Authorisation Assessments

Torbugesic 10 mg/ml Solution for Injection

Vm 42058/5176

13 December 2024	Substantial changes in the updated version of the ASMF of butorphanol tartrate.
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.