Veterinary Medicines Directorate

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Post Authorisation Assessments

Detogesic 10 mg/ml Solution for Injection for Horses

Vm 03379/5000

18 December 2025	Minor change to the production equipment for manufacture of the finished product.
26 March 2025	Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate) - changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place.
08 May 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
15 August 2023	Substantial changes in an updated version of an ASMF.
28 April 2021	Change in shape or dimensions of the container or closure (immediate packaging). Addition of a supplier of packaging components or devices.
26 September 2019	Changes to the QRD
18 December 2018	Renewal – UK as RMS.
28 March 2018	Deletion of the national representative Zoetis Italia s.r.l.. Change in the invented name of the veterinary medicinal product from 'Detogesic 10 mg/ml Solution for Injection for Horses' to 'Dorum 10 mg/ml Solution for Injection for Horses' in Italy.
15 June 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS
15 March 2016	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Minor changes to an approved test procedure of the finished product Addition of a new container type for the finished product. Addition of a 15 ml vial for the finished product.
25 February 2016	Change of Distributor from Pfizer Ltd to Zoetis UK Ltd
13 May 2015	Change of MAH address.
21 August 2013	MRP repeat use.
03 May 2013	Full European Renewal.
16 February 2012	To change the name of the Spanish manufacturer.
22 December 2011	Change in the re-test period/storage period or storage conditions of the active substance.
22 December 2011	Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance.
22 December 2011	Change in batch size (including batch size ranges) of active

	substance or intermediate.
28 August 2010	Change of Distributor from Fort Dodge Animal Health Limited to Pfizer Limited.
26 August 2010	To change the address of the marketing authorisation holder.
26 August 2010	To change the contact details of the QPPV.
26 August 2010	To change an existing pharmacovigilance system in the DDPS.
19 May 2010	Addition of a manufacturing site for all of the manufacturing processes of the finished product.
18 February 2009	To increase the shelf-life of the medicinal product.
21 August 2008	To change the medicinal product name in Austria.
04 August 2008	To add an additional site for quality control testing of finished product.