Veterinary Medicines Directorate

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Post Authorisation Assessments

Detogesic 10 mg/ml Solution for Injection for Horses

Vm 03379/4000

•	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.