Veterinary Medicines Directorate

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Post Authorisation Assessments

Equimidine 10 mg/ml Solution for Injection for Horses

Vm 25929/4000

•	15 August 2023	Substantial changes in an updated version of an ASMF.
•	14 April 2021	Addition of a supplier of packaging components or devices. Change in shape or dimensions of the container or closure (immediate packaging).
•	23 December 2020	Change in distributor details 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.
•	26 May 2017	Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	11 September 2015	Minor change to an approved test procedure for the finished product.
•	02 December 2014	Addition of a new vial type. Addition of a 15 ml vial size presentation.
•	04 December 2013	Change of distributor.
•	15 October 2013	Change in supplier of packaging components. Change in the specification parameters and/or limits of the finished product. Changes to the SPC.
•	21 December 2011	Grouped variation to increase batch size, to add identity tests for the starting materials, and to extend the re-test period.
•	12 October 2011	To name a second supplier for the product closure.
•	03 March 2011	Renewal procedure.
•	15 September 2010	Changes to the details of the marketing authorisation holder's pharmacovigilance system.
•	07 September 2010	Change of distributor.
•	12 May 2010	To increase the withdrawal period to, Meat and offal: 2 days and Milk: 12 hours.
•	22 July 2009	Change to the immediate packaging.
•	30 September 2008	SPC/Label changes (VetRegs 2005).
•	31 July 2008	Change in shelf life of the finished product.
•	19 May 2008	Change to batch release arrangements and quality control testing of finished product.
•	29 March 2006	Change of product name from Equisedan to

		Equimidine.
•	16 March 2006	Change of Distributor.