



Post Authorisation Assessments

Torphasol 10 mg/ml Solution for Injection for Horses

•	08 February 2022	Update of ASMF.
•	10 January 2018	Replacement of a site where batch control/testing takes place.
•	29 September 2015	Renewal – UK as CMS.
•	13 August 2014	To extend the shelf life of the finished product, from 24 months to 36 months.
•	10 June 2013	Change in distributor address.
•	25 April 2013	Up to 10 fold increase in batch size of active substance.
•	11 March 2013	Variation to make minor changes to the manufacturing process of the active substance to update the ASMF.
•	07 December 2012	To change the QPPV.
•	04 October 2012	To change the preservative used.
•	28 September 2011	Repeat Use Procedure.
•	02 March 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	02 March 2011	Changes to packaging material.
•	23 November 2010	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.
•	23 November 2010	Change in the name and/or address of a manufacturer of the active substance/starting material/reagent or intermediate used in the manufacture of the active substance.
•	23 November 2010	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
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