



Post Authorisation Assessments

Alizin 30 mg/ml Solution for Injection Vm 05653/5040

•	19 May 2021	Minor change in the manufacturing process of the active substance. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 November 2020	Repeat Use Application to add 1 new member state.
•	19 June 2020	Increase in batch size from 136 kg to 150 kg of the finished product.
•	24 July 2018	Change in RMS from UK to IE.
•	25 April 2017	Deletion of a non-significant specification parameter of the finished product. Change in the manufacturing process of the finished product.
•	12 February 2016	Renewal, UK as RMS
•	07 February 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	10 June 2011	Repeat use procedure.
•	25 August 2010	Approval of mock-ups.
•	14 December 2009	Renewal.
•	20 September 2007	Change of manufacturer of active substance or component of active substance.
•	06 April 2006	Addition of 1x10ml presentation.
•	25 May 2005	Repeat use procedure.
•	29 July 2004	Change in shelf life from 2 to 3 years.
•	07 July 2004	Change in finished product specifications.
•	26 March 2004	Mutual Recognition Procedure.
•	24 December 2002	Change in test method for starting material for the active substance and change in test method for finished product.
•	06 December 2002	Change in batch size of finished product.
•	05 December 2002	Changes in test methods for finished product and change in test method for starting material for the active substance.
•	27 June 2002	Change in test method for the control of finished product and addition of new pack size.
•	31 January 2002	Change in manufacturing process of the active substance, change in manufacturing process of the finished product and change of manufacturer of the active substance.

