Veterinary Medicines Directorate

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Post Authorisation Assessments

Alizin 30 mg/ml Solution for Injection for Dogs

Vm 05653/5040

25 August 2026	Introduction of a re-test period of the active substance supported by real time data. Change outside the approved specifications limits range for the active substance.
24 June 2026	Change in shape or dimensions of the container or closure of the sterile medicinal product.
05 January 2026	Alignment of product information with version 9.0 of the QRD template.
18 December 2025	Change in the name of an active substance manufacturer.
11 January 2025	Updated statements in 4.5i and 4.6 regarding rare cases of lack of efficacy which could lead to dystocia or uterine rupture and very rarely to fatal outcome.
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.