



Post Authorisation Assessments

Kepravine Dry Cow 250 mg Intramammary Suspension

•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	21 February 2018	Change in the RMS from UK to DE.
•	13 September 2017	Renewal – UK as RMS.
•	16 December 2016	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	28 September 2016	To tighten the shelf life limits for the active substance. Change in the specification parameters for the finished product. Addition of a test parameter for the finished product. Addition of a test limit for the finished product,
•	29 May 2015	Deletion of a manufacturing site of the active substance.
•	04 December 2014	Update to the DDPS.
•	4 June 2013	Variation to add an additional site for gamma irradiation of the active substance. This site is part of the same pharmaceutical group as the currently approved site.