



Post Authorisation Assessments

Adequan IM 500mg/5ml Solution for Injection Vm 36483/4002

12 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
02 April 2019	Change in RMS from UK to FR.
19 January 2015	Change to the MAH, from Novartis to Daiichi Sankyo Altkirch SARL.
16 January 2014	Change in address of the MAH in Portugal.
04 July 2013	Change of address for the Marketing Authorisation Holder (MAH) in France.
28 March 2013	Change of address for the MAH in Denmark, Finland, Norway and Sweden.
31 March 2011	Deletion of a manufacturer of the finished product responsible for QC testing and replacement of the manufacturer of secondary packaging.
24 March 2011	Change of the product name in Austria and Germany from Adequan 500mg/g ml Injektionslosung fur Pferde (Austria) and Adequan Vet., injektionsvaeske, oplosning (Germany) to Adequan IM 500 mg/5 ml
03 August 2010	Change of MAH and distributor from Janssen-Cilag Ltd to Novartis Animal Health UK Ltd
11 February 2010	Renewal
29 May 2009	Change of MAH address in Germany only.
06 March 2009	Change of name for the manufacturer of the active substance, minor changes to a test on the finished product and replacement of the manufacturing site for secondary packaging.
28 March 2008	Change to the manufacture of the finished product, specification and test methods. Change to the primary packaging.
27 February 2008	Change in the address of the MAH.
28 January 2008	Increase in the batch size of the finished product from 100L to 200L and 460L
04 December 2006	Change of the releasing site of the primary packaged product.
30 June 2005	Change in the name of the manufacturer.
17 March 2005	Renewal
13 March 2002	Submission of TSE Certificate
25 October 1999	Mutual Recognition procedure. UK as RMS. CMS's Austria,

	Belgium, Denmark, Germany, Greece, Spain, France, Italy, Luxembourg, Netherlands and Portugal.
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