Veterinary Medicines Directorate

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Post Authorisation Assessments

Adequan 100 mg/ml Solution for Injection

Vm 36483/4000

•	17 August 2022	Change in name and address of the manufacturer of the finished product.
•	22 July 2022	Change in immediate packaging of the finished product.
•	19 January 2015	Change to the MAH, from Novartis to Daiichi Sankyo Altkirch SARL.
•	09 February 2011	Variation to make minor changes to the SPC, labelling and package leaflet.
•	01 September 2010	Change of secondary packaging site. Deletion of the QC testing site Change in the site responsible for release.
•	28 July 2010	Variation to change the MAH and distributor
•	30 July 2009	Variation to change In Process controls, primary packaging, the finished specifications for release, shelf life and analytical methods.
•	16 February 2009	Variation to change a name and/or an address of a manufacturer of the active substance where no European Pharmacopoeia certificate of suitability is available. Minor change to the approved test method of the active substance. Replacement of a site for secondary packaging.
•	27 February 2008	Variation to change the address of the MAH
•	14 February 2008	Variation to bring the SPC and labels in line with the new legislation and to transfer the legal category from POM to POM-V
•	27 December 2007	Variation to increase the batch size for the finished product from 100 L to 200L and 460L
•	30 August 2006	Harmonisation of the active substance – changes to the tests, limits and analytical methods.
•	07 August 2006	Variation to change the site of batch release from
•	29 March 2006	Addition of two new test parameters
•	03 February 2006	Variation to tighten the limits for extractable volume on the release and shelf life finished product specifications.
•	31 January 2006	Minor amendments to the manufacture of the finished product. Amendment of the in-process controls for the finished product.
•	06 December 2005	Renewal
•	04 May 2004	Harmonisation of SPC
•	22 November 2002	Renewal

•	08 November 2001	Removal of wording referring to traumatic injury indication.
•	31 July 2001	Addition of a secondary assembly site
•	03 June 1998	Change in container specifications
•	14 July 1997	Change of assembly site of dosage form
•	07 May 1997	Change of withdrawal period to zero days
•	05 February 1997	Change in source of raw material for active substance manufacture.