

Post Authorisation Assessments

Duphacycline LA 20% Solution for Injection

•	29 May 2013	Submission of an updated Ph. Eur. Certificate of Suitability for and active substance from an already approved manufacturer
•	13 March 2012	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	19 January 2012	Changes to an existing pharmacovigilance system as described in the DDPS
•	28 July 2011	Submission of updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	23 February 2010	Change of MAH
•	15 October 2008	Renewal
•	14 December 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	04 November 2004	Renewal Change of composition of packaging component
•	12 August 2003	Change of withdrawal period for: Meat from pigs, from zero days to 18 days Milk from sheep, from zero days to 7 days Meat from sheep, from 21 days to 9 days Milk from Cattle, from 7 days to 10 days Meat from Cattle, from 28 days to 31 days
•	16 April 2003	Renewal
•	27 February 2001	Updates to the DMF of the active substance
•	17 February 1998	Change of name and address of the MAH
•	10 November 1995	Change to safety warnings