



Post Authorisation Assessments

Intradine 30.89% w/v Solution for Injection

•	20 September 2016	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	20 June 2012	Change in Distributor details.
•	01 August 2009	Addition of a manufacturer of the active substance
•	13 November 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	15 November 2007	Renewal
•	20 February 2007	Change of legal category from POM to POM-V
•	12 October 2005	Addition of a manufacturing site of assembly
•	28 August 2003	Renewal
•	22 July 2002	Renewal
•	20 February 2002	Change of withdrawal period for Meat from Pigs from 25 days to 42 days
•	01 October 2001	Change to withdrawal period for: Meat from Sheep to 18 days Meat from Cattle to 18 days Milk from Cattle to 156 hours
•	09 September 1998	Change to manufacturing site of assembly of the dosage form
•	08 May 1997	Change to manufacturer of the active substance