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Post Authorisation Assessments

Oxycare 3.6% w/w Cutaneous Spray Solution

•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 May 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	05 January 2016	Submission of a new Ph. Eur. certificate of suitability.
•	26 July 2013	Update to a distributor.
•	10 December 2012	Submission of an updated EDQM certificate of suitability for the active substance.
•	28 December 2011	Submission of an updated EDQM certificate of suitability for the active substance.
•	09 February 2011	Submission of an updated EDQM certificate of suitability for the active substance.
•	05 November 2008	Update to the product literature (immediate and outer packaging).
•	08 October 2008	Updates to the SPC and product literature to bring them into line with new legislation.
•	06 September 2007	Renewal
•	15 March 2007	Change in legal category from POM to POM-V
•	29 March 2006	Change to EDQM certificate of suitability.
•	11 January 2006	Change in packaging material.
•	08 November 2005	Addition of a site of assembly.
•	30 April 2003	Renewal
•	13 March 2003	Addition of a manufacturer of the active substance.