Veterinary Medicines Directorate

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Post Authorisation Assessments

Oxycare 200 mg/ml LA Solution for Injection for Cattle, Sheep and Pigs

•	23 January 2020	Deletion of a pack size of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Replacement to a test procedure for the finished product. Changes to a test procedure for the finished product. Change in the specification parameters and/or limits of the finished product. Change in the specification parameters and/or limits of the finished product. Changes in the composition (excipients) of the finished product.
•	23 January 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	23 January 2020	Changes to the withdrawal period of the veterinary medicinal product for all species.
•	23 January 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance.
•	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.
•	08 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.
•	24 February 2016	Change in test procedure for the finished product.
•	13 January 2015	Submission of a new or updated Ph. Eur. certificate of suitability.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS
•	19 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.
•	07 November 2007	Renewal

•	21 March 2007	Change in legal category from POM to POM-V.
•	10 November 2005	Addition of a sight of assembly of the finished product.
•	21 November 2003	Addition of a manufacturer/assembler of the finished product.
•	24 July 2003	Renewal
•	02 May 2003	Change to meat and milk withdrawal periods.
•	12 April 2002	Deletion of an active substance manufacturer.