Veterinary Medicines Directorate

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Post Authorisation Assessments

Cyclosol LA, 200 mg/ml Solution for Injection

Vm 16849/5009

•	03 April 2024	Update of the adverse events section, reflecting the outcome of a recommendation from the competent authority. Safety warnings, linked to the referral for the excipient "N-methyl pyrrolidone" have been included in the product information, as published in the Referral documents from EMA. Align the product information with version 9.0 of the QRD templates.
•	18 March 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	30 August 2018	Change in RMS from UK to NL.
•	23 July 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 March 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance. Deletion of a Ph. Eur. certificate of suitability for an active substance.
•	28 September 2016	Mock-ups approved. Change in distributor details.
•	17 September 2015	Changes in the composition (excipients) of the finished product
•	26 April 2013	Change in name and address of QPPV.
•	09 December 2009	Change of distributor.
•	03 April 2009	New/updated Ph. Eur. Certificate of Suitability for an active substance.
•	22 September 2008	Renewal.
•	21 April 2006	New/updated Ph. Eur. Certificate of Suitability for an active substance.
•	03 September 2004	Change of distributor.
•	17 October 2003	Mutual Recognition procedure.