



Post Authorisation Assessments

Cefenil 50 mg Powder and Solvent for Solution for Injection for Cattle

•	30 July 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	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.
•	16 September 2014	Change in the shelf-life of the product as packaged for sale, from 18 months to 36 months, and of the diluent, from 2 years to 36 months.
•	29 August 2014	Changes to the DDPS.
•	08 May 2014	Renewal procedure – Ireland as RMS.
•	29 June 2012	Addition of warnings to SPC and package leaflet following EU Commission decision.
•	29 May 2012	Change of Distributor.
•	14 August 2009	To change the MAH in France.
•	10 January 2007	Variation to increase the size of maximum blending volume of final product.
•	11 December 2006	Variation to change MAH in Denmark only.