Veterinary Medicines Directorate

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Post Authorisation Assessments

Dinalgen 300 mg/ml Oral Solution for Use in Drinking Water for Cattle and Pigs

•	May 2018	Increase in the shelf-life of the finished product as packaged for sale, from 3 years to 5 years.
•	16 October 2017	Introduction of a new pharmacovigilance system.
•	18 January 2017	Change in distributor details. From Laboratorios Dr. ESTEVE, S.A. to Ecuphar Veterinaria S.L.U.
•	02 December 2016	Change of Marketing Authorisation Holder from Laboratorios Dr. Esteve, S.A. to Ecuphar Veterinaria S.L.U.
•	19 July 2016	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product
•	09 July 2015	Submission of an updated certificate of suitability.
•	12 June 2014	To submit a new updated European Pharmacopeia Certificate of Suitability for the active substance.
•	16 January 2014	To change the name of the manufacturer of the finished product
•	23 December 2013	Renewal procedure – Spain as RMS.
•	16 November 2011	To change the name of the manufacturer of the finished product.
•	18 July 2011	Repeat Use Comm
•	08 April 2011	To submit a new updated European Pharmacopeia Certificate of Suitability for the active substance.
•	08 April 2011	To submit a new/updated European Pharmacopeia Certificate of Suitability for the active substance.
•	25 November 2010	To submit a new/updated European Pharmacopeia Certificate of Suitability for the active substance.
•	06 August 2010	Change in the batch size of the finished product.
•	10 June 2010	Deletion of a manufacturing site.
•	02 December 2009	Additional pack size of 100 ml.
•	25 September 2009	Change shelf life of finished product as packaged for sale.
•	10 July 2009	To submit a new/updated Ph. Eur certificate of suitability for an active substance from a new manufacturer.
•	26 March 2009	Add, replace or delete non-integrated devices