



Post Authorisation Assessments

Danilon Equidos 1.5g Granules for Top Dressing Vm 46037/4000

•	11 March 2022	Change in the address of the marketing authorisation holder from ECUPHAR VETERINARIA S.L.U. Avda. Rio de Janeiro 60-66 Planta 13, 08016 Barcelona (Spain) to ECUPHAR VETERINARIA S.L.U. C/Cerdanya, 10-12 Planta 6º, 08173 Sant Cugat del Vallés, Barcelona (Spain).
•	05 April 2017	Change in the manufacturer of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
•	22 June 2016	Introduction of a new pharmacovigilance system which has not been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	11 March 2016	Change in legal entity from Laboratonos Dr.Esteve, S.A. to Ecuphar Veterinaria S.L.U.
•	20 August 2013	Changes to in-process tests performed on the finished product
•	16 August 2013	Change specification of the finished product
•	20 December 2012	Change of distributor
•	04 July 2012	Replacement of a specification parameter for an excipient Deletion of non-significant specification parameters
•	27 June 2012	Changes to the manufacture of the active substance
•	24 May 2012	Minor change in the manufacturing process of the finished product
•	07 October 2009	Correction to section 4.9 of the SPC
•	17 December 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	04 October 2006	Renewal
•	05 August 2005	Change to measuring device
•	06 October 2004	Change of distributor
•	07 May 2004	Change of manufacturing process of the finished product