Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

Gestavet 400/200 IU Lyophilisate and Solvent for Solution for Injection for Pigs Vm 57571/4000

•	06 February 2023	Change of MAH from LABORATORIOS HIPRA, S.A. Avda. la Selva, 135, 17170 Amer (Girona), Spain to BIOGÉNESIS GLOBAL, S.L., Manuel Pombo Angulo, 28 28050 Madrid, Spain.
•	15 July 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	04 February 2016	Change in the name of the UK local representative.
•	01 April 2015	Renewal procedure – Spain as RMS.
•	19 November 2014	Addition of local representative information to the product packaging and leaflet.
•	31 October 2014	Deletion of a manufacturing site for an active substance.
•	06 February 2014	Addition of an active substance manufacturer, and to adjust the process ensuring quality of the active substance.
•	22 January 2014	Addition of a manufacturer. Change in the manufacture of the active substance.
•	21 May 2012	Addition of a pack size of carton boxes containing 10 vials of powder and carton boxes containing 10 vials of solvent.