Veterinary Medicines Directorate

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Post Authorisation Assessments

Gestavet 400/200 IU (40 IU/ml + 80 IU/ml) Lyophilisate and Solvent for Solution for Injection for Pigs

Vm 57571/4000

27 May 2026	Clarification in ATC vet code. (GB & NI)
27 May 2026	One-off alignment of the product information with version 9.1 of the QRD template. (GB & NI)
13 March 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).
04 March 2025	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB).
04 March 2025	Change in the address of the Marketing Authorisation Holder from 28, Manuel Pombo Angulo St, 3 & 4 floor, 28050 Madrid, Spain to 6, Quintanadueñas St, 1 floor Bloque A, 28050 Madrid, Spain. (GB and NI).
19 December 2024	Deletion of the Local Representative address. (GB and NI).
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.