



Post Authorisation Assessments

Genestran 75 micrograms/ml Solution for Injection for Cattle, Horses and Pigs Vm 24745/4010

•	19 March 2024	Addition of a secondary packaging site for the finished product. (NI)
•	08 June 2023	Addition of a secondary packaging site of a finished product. (GB)
•	21 July 2021	Updated ASMF.
•	09 December 2020	Tightening of specification limits of an active substance.
•	01 May 2019	Addition of a supplier of packaging components or devices. Addition of a manufacturer responsible for batch release including batch control. Addition of a site where batch control/testing takes place. Addition of secondary packaging site of the finished product. Increase in batch size (including batch size range) of the finished product. Addition of a manufacturing site of the finished product. Addition of a manufacturing site of the finished product.
•	10 January 2018	Replacement of a site where batch control/testing takes place.
•	23 February 2017	Change in the SPC, labelling or package leaflet due to new data.
•	06 July 2016	To submit updated ASMF for currently authorised active substance manufacturer
•	22 June 2016	Addition of a manufacturer of the active substance.
•	09 September 2013	Extension of shelf life of the finished product as packaged for sale from 2 years to 3 years.
•	07 May 2013	Addition of a 50ml glass vial presentation, with cartons of 1 vial available.
•	02 April 2013	Addition of a batch size.
•	07 December 2012	To change the QPPV.
•	26 October 2011	Repeat Use Comm.
•	07 April 2011	Changes to the primary packaging material not in contact with the finished product.
•	07 April 2011	Changes to an existing pharmacovigilance system.
•	11 March 2011	Renewal – UK as CMS
•	30 September 2010	To add a pack size of the finished product – Cardboard box with 5 vials of 20 ml
•	28 April 2010	Repeat Use Comm
•	06 October 2009	To change the Marketing Authorisation Holder.
•	24 August 2009	To make a minor change in the test procedure of the finished product.
•	24 August 2009	To change the address of the manufacturer of the finished

		product.
•	08 July 2009	To replace the batch release site.