April 23rd, 2024

Dear Colleagues/Customers,

As communicated in Takeda's letter dated January 23rd, 2024, a drug shortage situation occurred impacting GAMMAGARD® S/D (5 mg/vial DIN 02231470, 10 mg/vial DIN02231471) due to unexpected interruption of the manufacturing of the Baxter diluent, previously packaged with GAMMAGARD® S/D product.

To maintain product access for impacted patients, Takeda Canada was authorized to distribute a limited amount of Canadian-labelled GAMMAGARD® S/D product packaged with sterile water for injection (sWFI) manufactured by a different supplier, in advance of the related regulatory approval.

Takeda Canada would like to inform all customers that the addition of Siegfried Hameln as a new supplier of sWFI for GAMMAGARD® S/D received approval by Health Canada on January 16th, 2024. Therefore, the next supply of GAMMAGARD® S/D contains Health Canada approved product labels. Siegfried Hameln supplies two sWFI fill sizes (96 mL and 192 mL) that are co-packaged with GAMMAGARD® S/D.

The next supply of GAMMAGARD® S/D packaged with sWFI from Siegfried Hameln has the lot number BE08D019AF and expiry of 2025-08-27.

GAMMAGARD® S/D packaged with Hameln sWFI should be used in the same manner as product packaged with Baxter sWFI. To ensure safe use of the GAMMAGARD® S/D product, please refer to the GAMMAGARD® S/D Product Monograph for labelling information, available in English and French at https://www.takeda.com/en-ca/ggsdpm and https://www.takeda.com/fr- ca/ggsdmp. If additional information is required, please contact Medical Information at 1.800.268.2772 or medinfoCA@takeda.com.

In case of any adverse event suspected, the details and the Medical Information contact details can be found online at https://www.takeda.com/en-ca1what-we-do/our/medicines/shire- products/. Suspected side effects can also be directly reported by email to AE.CAN@takeda.com.

To report adverse event or side effects to Health Canada, please complete the form online via https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html or by calling toll-free at 1-866-234-2345.

Sincerely,

Jefferson Tea, PhD, MBA
Vice President/Head of Medical & Scientific Affairs
Takeda Canada Inc.
22 Adelaide Street West, suite 3800
Toronto, ON M5H 4E3, Canada
Telephone: 1.647.798.2200 or 1.866.397.4473
https://www.takeda.com/en-ca