Better Health, Brighter Future

7th February 2022

Direct Healthcare Professional Communication (DHPC)

GAMMAGARD S/D 10g (human normal immunoglobulin G (IgG); PL 34078/0006) – do not use administration sets supplied with certain batches due to a quality defect associated with sterility; caution required to minimise the risk of infection

Dear Healthcare Professional,

Takeda UK Ltd. (acting on behalf of Baxalta Innovations GmbH) and in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary:

- **Administration sets co-packaged with certain GAMMAGARD S/D 10g batches currently available in the UK are impacted by a quality defect related to sterilisation**
- **Do not use administration sets packaged together with the GAMMAGARD S/D 10g batches listed in Annex 1 – affected administration sets should be disposed of in line with local policies**
- **To minimise risk of infection, alternative administration sets with a similar filter should be used when administering affected batches – see page 3 for specifications of alternative administration sets**
- **The medicine within batches itself is not affected.**

Background on the safety concern

GAMMAGARD S/D 10g powder and solvent for solution for infusion contains human normal immunoglobulin G (IgG). GAMMAGARD S/D is used for the following therapeutic indications:

Replacement therapy in:

- Primary immunodeficiency syndromes such as:
  - congenital agammaglobulinaemia and hypogammaglobulinaemia
  - common variable immunodeficiency
  - severe combined immunodeficiency
  - Wiskott Aldrich syndrome

- Myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections
- Children with congenital AIDS and recurrent infections

Immunomodulation:

- Idiopathic thrombocytopenic purpura (ITP), in children or adults at high risk of bleeding or prior to surgery to correct the platelet count
- Guillain-Barré syndrome
- Kawasaki disease
- Allogeneic bone marrow transplantation

GAMMAGARD S/D contains only trace amounts of IgA. For patients who require immunoglobulin treatment with very low IgA concentrations, alternative treatment options are limited.

As a result of EU action by Baxter for administration sets affected, Takeda is distributing this DHPC to advise of the following:

- Administration sets affected that are packaged together with the GAMMAGARD S/D 10g batches listed in Annex 1 should not be used
- Equivalent administration sets should be used for administration of the GAMMAGARD S/D 10g batches listed in Annex 1
- Refer to the Summary of Product Characteristics (SmPC) and package leaflet instructions below and as per Annex 2

The health risk assessment conducted by Takeda in relation to the incident reported by Baxter and its impact on GAMMAGARD S/D concluded that the potential risk to the patient is negligible and the benefit-risk profile of GAMMAGARD S/D remains positive. However, Takeda is advising that the Baxter administration sets affected should not be used during administration of Takeda GAMMAGARD S/D 10g batches.

<u>SmPC and package leaflet instructions</u>

SmPC section 6.6 ‘Special precautions for disposal and other handling’ and package leaflet section 6 ‘Contents of the pack and other information’ states:

Administration - use aseptic technique 5.0 g, 10.0 g Sizes

‘Follow the direction insert for use, which accompanies the administration set provided in each package. If another administration set is used, ensure that the set contains a similar filter’.

Use of Alternative Administration sets

The Baxter text for the administration set supplied with the GAMMAGARD S/D product is included in Annex 2. It specifies that the solution administration set is a Non DEHP, air vented, 15 micron filter with a rotary luer lock.

Equivalent administration sets that meet the criteria described can be used in place of the Baxter Administration set included with the Takeda GAMMAGARD S/D product (for example, B Braun Intrafix Safe Set 4063000). Alternative administration sets to be used should meet the standards set out in *BS EN ISO 8536-4: 2020 Infusion equipment for medical use Part 4: Infusion sets for single use, gravity feed*.

Call for reporting

Please report suspected adverse drug reactions (ADRs) or suspected defective medicines to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website: www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card Scheme.

Company contact point(s)

Dr Simon Meadowcroft
Medical Director UK & Ireland
Mobile: +44 (0)7766526793
1 Kingdom Street
London W2 6BD

Takeda UK Ltd. Medical Information e-mail:
medinfoemea@takeda.com
Med Info. direct line: +44 (0) 3333 000 181
Drug safety e-mail:
AE.GBR-IRL@Takeda.com

Should you have any queries regarding this notification, please contact us using the details provided above.

Yours sincerely,

Dr Simon Meadowcroft
Medical Director UK & Ireland
Takeda UK
BSc MBChB (hons) MRCGP MFPM

Annex 1: GAMMAGARD S/D 10 g Batch Listing

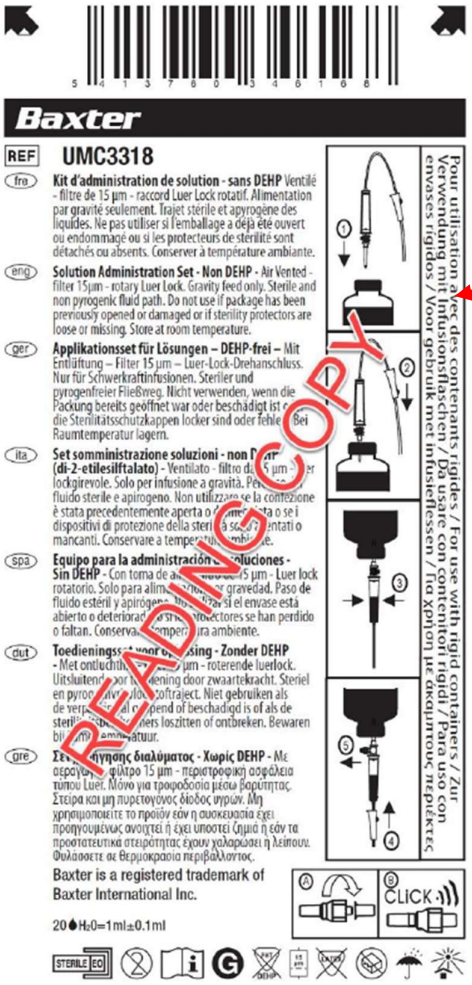
This safety issue relates to the following batches of GAMMAGARD S/D 10 g

PRODUCT LICENCE NUMBER	NATIONAL CODE	BATCH NUMBER	DATE OF MANUFACTURE	EXPIRY DATE	BATCH SIZE
PL 34078/0006	UK	LE08W005AL	16/02/2020	31/01/2022	30
PL 34078/0006	UK	LE08W009BB	22/03/2020	28/02/2022	17
PL 34078/0006	UK	LE08W009AK	22/03/2020	28/02/2022	10
PL 34078/0006	UK	LE08W011AS	06/04/2020	31/03/2022	30
PL 34078/0006	UK	LE08W027AF	20/09/2020	31/08/2022	17
PL 34078/0006	UK	LE08W031AH	19/10/2020	30/09/2022	22
PL 34078/0006	UK	LE08W038AM	06/12/2020	30/11/2022	18
PL 34078/0006	UK	LE08W038AL	06/12/2020	30/11/2022	18
PL 34078/0006	UK	LE08W038AJ	06/12/2020	30/11/2022	22
PL 34078/0006	UK	LE08X008AH	21/03/2021	28/02/2023	19

Annex 2: Baxter Administration set co-packaged with GAMMAGARD S/D 10 g

Pack contents

Administration Set



Administration Set - Blister Pack backing