



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

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- 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.

SmPC and package leaflet instructions

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/SystemOne/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.

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

Yours sincerely,



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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

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

Pack contents



Administration Set

5 14 1 3 7 6 0 3 4 6 1 0 8

Baxter

REF UMC3318

(fr) **Kit d'administration de solution - sans DEHP Ventilé**
- filtre de 15 µm - raccord Luer Lock rotatif. Alimentation par gravité seulement. Fluide stérile et apyrogène des liquides. Ne pas utiliser si l'emballage a déjà été ouvert ou endommagé ou si les protecteurs de stérilité sont détachés ou absents. Conserver à température ambiante.

(eng) **Solution Administration Set - Non DEHP - Air Vented - filter 15µm - rotary Luer Lock. Gravity feed only. Sterile and non pyrogenic fluid path. Do not use if package has been previously opened or damaged or if sterility protectors are loose or missing. Store at room temperature.**

(ger) **Applikationsset für Lösungen - DEHP-frei - Mit Entlüftung - Filter 15 µm - Luer-Lock-Drehanschluss.** Nur für Schwerkraftinfusionen. Steril und pyrogenfreier Fließweg. Nicht verwenden, wenn die Packung bereits geöffnet war oder beschädigt ist oder die Sterilitätsschutzkappen locker sind oder fehlen. Bei Raumtemperatur lagern.

(ita) **Set somministrazione soluzioni - non DEHP (di-2-etilossifalato) - Ventilato - filtro di 15 µm - per lock a rotazione. Solo per infusione a gravità. Fluido sterile e apirogено. Non utilizzare se la confezione è stata precedentemente aperta o danneggiata o se i dispositivi di protezione della sterilità sono mancanti o mancanti. Conservare a temperatura ambiente.**

(spa) **Equipo para la administración de soluciones - Sin DEHP - Con toma de alimentación 15 µm - Luer lock rotatorio. Solo para alimentación por gravedad. Paso de fluido estéril y apirógeno. No usar si el envase está abierto o deteriorado o si los protectores se han perdido o faltan. Conservar a temperatura ambiente.**

(dut) **Toedieningsset voor oplossingen - Zonder DEHP**
- Met ontluifscherm, 15 µm - roterende luerlock. Uitsluitend voor toediening door zwaartekracht. Steriel en pyrogenvrij vloeistoftraject. Niet gebruiken als de verpakking al eerder is geopend of beschadigd is of als de steriliteitsbeschermingen loszitten of ontbreken. Bewaren bij kamertemperatuur.

(gre) **Σετ χορήγησης διαλύματος - Χωρίς DEHP - Με αερίωση φίλτρο 15 µm - περιστροφική σφαιρική τρυπήση Luer. Μόνο για τροφοδότηση μέσω βαρύτητας. Στείρα και μη πυρετογόνος δίοδος υγρών. Μην χρησιμοποιείτε το προϊόν εάν η συσκευασία έχει προηγουμένως ανοιχτεί ή έχει υποστεί ζημιά ή εάν τα προστατευτικά στειρότητας έχουν χαλαρώσει ή λείπουν. Φυλάσσετε σε θερμοκρασία περιβάλλοντος.**

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20 ● H₂O=1ml±0.1ml

STERILE

Click

Administration Set - Blister Pack backing