Instituto Grifols, S.A.
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Batch Recall

Product	Authorisation No.	Batch No	Expiry date
Flebogamma DIF 100 mg / ml solution for infusion (10 g / 100 ml vial)	EU/1/07/404/007	G04K139941	22/09/2027
Flebogamma DIF 100 mg / ml solution for infusion (20 g / 200 ml vial)	EU/1/07/404/008	G04K192351	18/12/2027

September 11, 2026

Dear Pharmacist,

We wish to advise you that the above-listed batch numbers of Flebogamma DIF 100 mg / ml solution for infusion are being recalled with immediate effect.

This recall is to **patient level**, and the action has been agreed with the Health Products Regulatory Authority.

The two affected batches are being recalled as a precaution following increased reporting of hypersensitivity type reactions in association with these batches. To date, no manufacturing issues or quality defects have been identified.

Other batches currently being distributed are not affected by this recall and can therefore be used.

You are requested to perform the following actions:

1. For stock within your pharmacy or facility, immediately identify and quarantine any units of the above-listed batches. For hospital pharmacies, clinics, nursing homes and other such facilities, this includes units at wards, clinics and any other relevant locations within your facility.
2. Identify patients to whom these batches may have been dispensed. Contact those patients or their carers via telephone to request they return any unused units to your pharmacy.
3. Please bring the contents of this letter to the attention of relevant healthcare professionals.
4. If you have supplied any units of these batches to another pharmacy or facility, please forward a copy of this recall letter to them and request they return any unused units to your pharmacy.
5. Contact your wholesaler to arrange uplift of the quarantined units within the next 30 days. Credit will be arranged at that time.

Replacement unaffected stock is available to order at this time.

Hypersensitivity reactions are a known risk with Flebogamma DIF products. Healthcare professionals are reminded of the advice contained in the current Summary of Product Characteristics for Flebogamma DIF regarding the monitoring and management of hypersensitivity reactions during and following administration- see Flebogamma DIF product information available here: Flebogamma DIF, INN-human normal immunoglobulin

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Please report any suspect adverse reactions to Grifols at gds@grifols.com and to the HPRA at medsafety@hpra.ie.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Andrew O'Connell (Caragen Ltd) at telephone number 087 254 1493.

Yours sincerely,

Anna Mas

Digitally signed by Anna Mas
Date: 2026.09.11 18:30:14 +02'00'

Anna Mas Albaiges
Substitute Qualified Person
Instituto Grifols S.A.