Be DIFferent

Not all patients are alike

Flebogamma® DIF
Human Normal
Immunoglobulin (IVIg)
50 mg/ml 100 mg/ml

GRIFOLS

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Not all **patients** are **alike**; and **not** all **IVIGs** are **alike** either

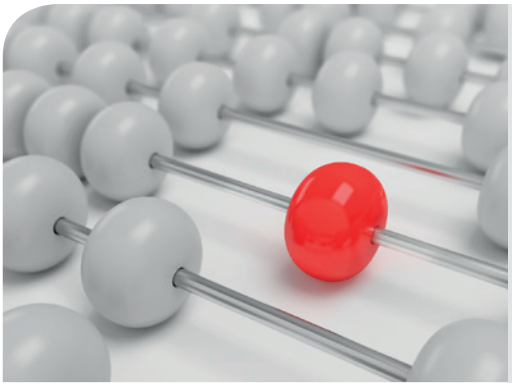
Generally, IG infusions are well tolerated[1]; however, there are **risk factors** known to be **associated with the major complications or adverse effects of IVIG**[2].

	Risk factors	IVIG infusion considerations
	Advanced age Hypertension Coronary artery disease Diabetes mellitus Metabolic syndrome Hormone replacement therapy History of stroke Hemolysis History of transient ischemic attack Immobility History of deep vein thrombosis History of bypass surgery	Low concentration product Slow infusion rate Reduced sodium content Ensure the patient is well hydrated prior to infusion Spread the dose over more sessions Sucrose-free preparation Low anti-A/B preparation
	Pre-existing renal insufficiency Concomitant nephrotoxic drugs Volume depletion Paraproteinaemia Advanced age (>65) Diabetes mellitus Sepsis	Low concentration product Sucrose-free preparation Reduced rate of infusion Total IVIG dose should be reduced and spread over several days
	History of frequent headaches, migraine, aseptic meningitis	Low concentration product Slow infusion rate Administer IVIG with a space of 1 or 2 days between each infusion Consider anti-migraine medications before and during IVIG infusion

Slow infusion rate of low IVIG concentration products and hydration, especially in high-risk patients, may **reduce the risk of renal failure**, **thromboembolic events**, and **aseptic meningitis**[3]

Patients do not equally tolerate different IVIG preparations

IVIG preparations are **not** all **equally well tolerated:**[4]



Not all IVIGs are the same[1]
IVIGs must be considered individual therapies, not generic drugs.[5]

IVIG products are not interchangeable[5]
Different manufacturing processes make nonequivalent plasma-derived products and the final composition of IVIG products has resulted in varying tolerability profiles.[1]

Product changes may improve adverse event profiles[5]
As the manufacture of the individual products is different, individual patients may experience adverse events in response to some, but not other products.

Flebogamma® DIF may be the **appropriate choice**

According to a **recent prospective study**, including immunodeficiency, autoimmune disease and bone marrow transplant (BMT) patients, both **Flebogamma® DIF 5% and 10% were well tolerated**[6]

	Flebogamma® DIF 5%	Flebogamma® DIF 10%
Patients	34	32
Patients with ADRs* (potentially treatment-related AEs)	**3 (8.82%)**	**9 (28.13%)**
Infusions	135	130
Infusions with ADRs (potentially treatment-related AEs)	**3 (2.22%)**	**24 (18.46%)**

*ADRs: potential related adverse events. All ADRs were defined as non-severe

- **In Flebogamma® DIF 5%,** frequency of infusions with potentially **treatment-related AEs was low (2.2%)** and **no headaches** were reported[6]
- **In Flebogamma® DIF 10%**, percentage and type of **AEs** reported in this study **were consistent with other 10% IVIGs**[6]
- **Flebogamma® DIF 5%** may be an **appropriate choice for** many of **your patients** including those **who cannot tolerate a 10% IVIG**

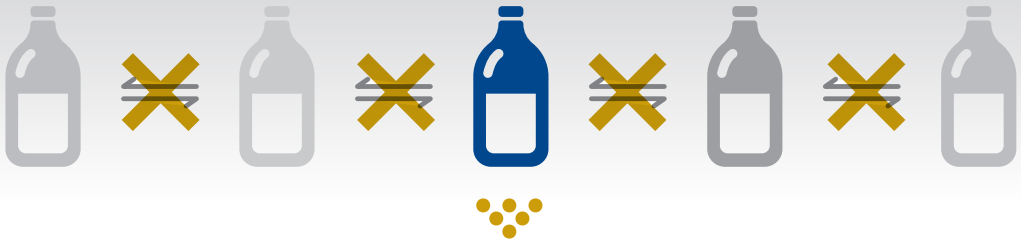
In patients with risk factors, tolerability is particularly important

What makes **Flebogamma® DIF** different?

- Uses **sorbitol as stabilizer** that does not elevate blood glucose or insulin levels[7] (no sucrose, no maltose and no glucose)
- Undergoes pasteurization, a safety step with the capacity to inactivate clotting factors, which **helps limit the risk of thromboembolic events**[8]
- Contains **trace amounts of sodium** (<3.2 mmol/l)[9]
- Contains **trace amounts of IgA***[10], being one of the IVIGs with the lowest concentrations of IgA[9]
- **Osmolality is within the physiological range** (240-370 mOsm/kg)[11,12]

*Mean values (mg/ml):
Flebogamma® DIF 5%: 0.0031±0.0001, n=253.
Flebogamma® DIF 10%: 0.0031±0.0006, n=127.

IVIG products are not interchangeable[5]



Flebogamma® DIF is well tolerated and shows a low frequency of AEs[6]

See the SPC/package insert inside

Flebogamma® DIF

Human Normal Immunoglobulin (IVIg)

50 mg/ml **100** mg/ml

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