IMMUNE GLOBULIN (IG) therapies have evolved into one of the most promising therapies of all times. Although current products on the market collectively carry U.S. Food and Drug Administration (FDA)-approved indications for only six different disease states, IG is an accepted use of treatment for many more. In part because of its success in treating immune-mediated diseases, IG is currently being studied as a possible treatment in more than 50 active clinical trials, according to www.clinicaltrials.gov.

A Unique Drug

IG is a unique drug. Currently, there are only a handful of manufacturers approved to sell IG in the U.S., and there are no generic forms of it; they all are considered name brand. In addition, although all manufacturers must meet at least the same criteria for safety, the ingredients and manufacturing processes can and do vary. As a result, no two IG products are exactly the same. And while many practitioners still consider all IG products to be clinically equivalent, they are not pharmaceutically equivalent.¹

Mandated Warnings

All IG products are FDA-mandated to carry a black-box warning for acute renal dysfunction and failure. However, it is thought that such problems are more often associated with products containing sucrose, which can be used to stabilize the IG proteins. As a result, most IG products in the market today do not contain sucrose.

Additionally, all IG products carry a warning stating that the product is not indicated for patients with a selective IgA deficiency that are known to carry antibodies against IgA and who have a history of hypersensitivity. Patients reading the package insert for the first time should understand that having a low IgA level and having antibodies to IgA is not the same thing. Regardless, doctors prescribing IG for naive patients who have a low IgA level may decide to use a product with a low IgA level as a precaution.

Extra Precautions

Choosing a product carefully for patients with comorbidities such as diabetes, renal dysfunction, heart failure and vascular disease can be especially important. In particular, the amount of sodium and sucrose can affect the osmolality of the product, which in turn can affect the patient. It is felt that the closer an IG product’s osmolality is to the human plasma, which is 280 to 300 mOsm/kg, the better it may be tolerated.

Besides osmolality, patients with diabetes using a glucometer to monitor their diabetes need to be aware that an infusion with an IG containing maltose could lead to falsely high sugar readings. Specifically, monitors that use test strips containing the enzyme glucose dehydrogenase (GDH)-pyrroloquinoline quinone (PQQ) falsely interpret maltose as glucose, producing an unreliable reading. A falsely high reading could lead to an inappropriate administration of insulin, resulting in life-threatening hypoglycemia. The FDA has recommended that healthcare facilities not use test strips containing GDH-PQQ.² Despite that, some glucometers, mainly those manufactured by Roche, continue to use the GDH-PQQ enzyme in their test strips. To see a list of all test strips made with GDH-PQQ, go to http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm176992.htm#attachment.

Shelf life is another pharmaceutical element that determines the cost of distribution and which drug is provided to the patient. Most IG products carry at least

Choosing an Immune Globulin Product

By Kris McFalls
a 24-month or longer shelf life. However, for some products, refrigeration is necessary for all or at least part of the shelf life for them to maintain stability.

**Considering the Needs of the Patient**

Many factors need to be considered when choosing an IG product. But, by far, the most important considerations are the needs of the patient. While some products may be better tolerated than others, each patient may exhibit an individual tolerability of one product over another.

**Baxter Healthcare Corp.**

Gamagard S/D is approved for intravenous administration for primary immunodeficiency, chronic lymphocytic leukemia, immune thrombocytopenic purpura and Kawasaki syndrome.  
(800) 422-9837; www.baxter.com/healthcare_professionals/products/gamagard_sd_5.html

**Baxter Healthcare Corp.**

Gamagard Liquid 10% is approved for intravenous and subcutaneous use for primary immunodeficiency.  
(800) 422-9837; www.gammagardliquid.com

**Bio Products Laboratory**

Gammaplex is approved for intravenous administration for primary immunodeficiency.  
(800) 843-7477; www.gammaplex.com

**CSL Behring**

Carimune NF is approved for intravenous administration for primary immunodeficiency and for acute and chronic immune thrombocytopenic purpura.  
(800) 683-1288; www.cslbehring-us.com

**CSL Behring**

Hizentra is approved for subcutaneous administration for primary immunodeficiency.  
(800) 683-1288; www.hizentra.com

**CSL Behring**

Privigen is approved for intravenous administration for primary immunodeficiency and immune thrombocytopenic purpura.  
(800) 683-1288; www.privigen.com

**Grifols USA**

Flebogamma DIF 5% and Flebogamma DIF 10% are approved for intravenous administration for primary immunodeficiency.  
(888) 474-3657; www.grifolsusa.com

**Grifols USA**

Gamunex-C is approved for intravenous and subcutaneous administration for primary immunodeficiency. Gamunex-C is also approved for intravenous administration for immune thrombocytopenic purpura and chronic inflammatory demyelinating polyneuropathy.  
(888) 694-2686; www.gamunex-c.com

**Kedrion Biopharma**

Gammaked is a 10% solution approved for intravenous administration for the treatment of primary immunodeficiency, idiopathic thrombocytopenic purpura and chronic inflammatory demyelinating polyneuropathy, and for subcutaneous administration to treat primary immune deficiency. The product was launched in the U.S. market in August.  
(888) 694-2686; www.gammaked.com

**Octapharma**

Octagam 5% is approved for intravenous administration for primary immunodeficiency.  
(800) 826-6905; www.octapharma.com

**References**


**Directory of IG Products**

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