Immune Globulin Therapy: a Brief Introduction

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Immune globulin (IG) therapy is a real lifesaver! This article answers some frequently asked questions about this important therapy: It defines what IG is, how IG is prepared, IG brand names, methods of administering IG, and currently effective therapeutic uses of IG.

What Is Immune Globulin?

Immune globulin is a purified component of the blood. It is used in a number of disorders, including immune deficiency diseases, such as hypogammaglobulinemia, and a multitude of autoimmune disorders, such as primary immune deficiency diseases, peripheral neuropathies, Guillain-Barré syndrome, myositis, multiple sclerosis, etc.

Immune globulin is also known as gamma, gamma-globulin, immune globulin intravenous, IVIG, IgG and IGIV. Whatever name you give it, immune globulin is a sterile solution of highly purified proteins extracted from large pools of human plasma, the liquid portion of blood, collected from 50,000 to 60,000 people. All donors are screened according to American Red Cross standards, and their blood is tested for evidence of any transmissible or infectious diseases. Any blood suspected of having a problem, such as HIV or hepatitis, is discarded.

Immune globulin naturally occurs in the human body. It is made of protein molecules, also called antibodies, produced by B cells when they respond to a foreign substance in the body. Antibodies are a part of our body's multifaceted, amazingly coordinated immune system. Antibodies defend us, in coordination with other immune system cells (T-cells, phagocytes and complements), against a broad spectrum of bacteria, fungi, parasites and viruses. The five types of immune globulins—IgG, IgA, IgM, IgE and IgD—each defend us against these "invaders" differently.

How Is IG Derived?

Therapeutic immune globulin is produced from plasma recovered from whole human blood. First, all red and white cells and platelets are removed from the blood. Then the remaining liquid plasma is chemically treated to precipitate purified immune globulins (antibodies). The majority of the immune globulin produced is of the IgG class. Many fractionation and filtering processes are used to separate out all other blood proteins and kill any viruses or germs that may remain in the plasma.

The U.S. Food and Drug Administration (FDA) is the federal organization that approves the use of therapeutic agents such as IG. FDA approval is given for use of a product for specific diseases, under certain conditions and via certain methods of administration. The approval process is strenuous, requiring well-controlled patient studies documenting that the product is safe and effective.

Currently, IG is FDA-approved for intramuscular or intravenous delivery. A physician must prescribe and monitor its use, because FDA-approved doses are different for each patient, based on body weight and the condition for which they are being treated. Some physicians have determined that not all patients tolerate intravenous IG delivery well. In these cases, they recommend subcutaneous administration (SCIG), for which the FDA recently approved a product.

What IG Products Are Available?

IG is available in several brand names, made by various pharmaceutical companies. The following IG products are FDA-approved for use in the United States:

Product	Manufacturer
Carimune NF	ZLB Behring
Flebogamma	Grifols
Gammagard 5% S/D	Baxter
Gammagard 10% S/D	Baxter
Gammagard Liquid	Baxter
Gammar-P IV	ZLB Behring
Gamunex	Talecris
Octagam	Octapharma
Polygam S/D	Baxter
Vivaglobin	ZLB Behring

When Is IG used?

IG is used in the treatment of primary immune deficiencies and autoimmune diseases that disrupt the delicate balance of the operation of the human immune system. IG is also used to treat a variety of infections—bacterial and viral.

The members of the primary immunodeficiency committee of the American Academy of Allergy, Asthma and Immunology, in their paper on the appropriate use of IG,[1] list the uses of IG for disease states classified into various categories, including ***Definitely Useful, Probably Useful and May Provide Benefit***. Their classifications are based on currently available evidence. As additional evidence becomes available, benefit categories may change. Those classifications for which benefits have been proven are listed at right.

Definitely Useful

- Primary immunodeficiency
- Idiopathic thrombocytopenic purpura
- Graves' ophthalmopathy
- Demyelinating polyneuropathies
- Kawasaki disease

Probably Useful

- Chronic lymphocytic leukemia with reduced IgG and history of infections
- Prevention of bacterial infection in HIV-infected children
- Dermatomyositis and polymyositis
- Myasthenia gravis and Eaton-Lambert myasthenia syndrome
- Established bacterial sepsis
- Toxic epidermal necrolysis and Stevens-Johnson syndrome

May Provide Benefit

- Prevention of neonatal sepsis
- Post transfusion purpura
- Autoimmune cytopenias
- Systemic lupus
- Severe rheumatoid arthritis
- Antiphospholipid antibody syndrome in pregnancy
- Antineutrophil cytoplasmic antibody syndromes
- Severe persistent high dose steroid-dependent asthma
- Multiple sclerosis (relapsing-remitting)
- Intractable childhood epilepsy
- Prevention of infection and acute graft versus host disease post-hematopoetic stem cell transplantation
- Prevention of acute humoral rejection in renal transplantation
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)

Immune globulin is indeed a lifesaver! For more information about this amazing therapeutic, visit the following websites:

www.medlineplus.gov

www.immune-globulin.com

www.baxter.com

www.grifolsusa.com

www.octapharma.com

www.talecris.com

www.zlbbehring.com

[1]*Orange, J.S., MD (editor) Practice paper on the appropriate use of intravenously administered immunoglobulin (IGIV), generated by the primary immunodeficiency committee of American Academy of Allergy, Asthma and Immunology, Aug 2005, http://www.aaaai.org/media/resources/academy_statements/practice_papers/igiv.pdf.*