

# *How to keep an* INFUSION LOG



Intravenous Immune Globulin (IVIg)

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## The Value of Keeping Records

Excellence in health care depends on the cooperative efforts of a number of different individuals including the patient and his/her physicians, pharmacists, nurses and family members. Traditionally, each has had a different, and complementary, role to play in attaining and maintaining the best possible health for the patient. However, more recently some of the responsibilities traditionally held by one member of the "health care team" have been shared by some of the others, including the patient! For example, some patients have a number of different doctors, each prescribing different medications for different problems, and it is in the patient's best interest to keep track of those medications their possible side effects and interactions with each other.

The same value can be found in keeping track of your Intravenous Immune Globulin (IVIG) infusions. Each of the manufacturers prepares IVIG in a different way using different purification procedures, viral inactivation steps, and different ways of packaging the final product, some being dry powders and others in liquid form. Thus, although they all contain immunoglobulin and are excellent in replacing the proteins that the patients can not make themselves, they are nonetheless, unique in other ways.

There are real benefits to keeping track of which brand of IVIG you receive, how much you receive, and how often you receive it. For example, some patients may tolerate one manufacturer's IVIG product better than another, and knowing which

brand you have received allows you and your doctor to determine which brand is best for you. Also, in some instances you may need to receive your dose of immune globulin a few days early or late and recording the dates of your infusions allows you to maintain a relatively regular schedule. In other instances, you may need to switch physicians and/or infusion sites or services, and keeping track of the brand, dose and frequency of infusions allows ongoing consistent infusions. Finally, in rare instances, questions relating to the donor pool and the manufacturing process may arise and knowing which brand and lot number of that brand you have been receiving will be of value in determining whether you have received the specific IVIG preparation under question.

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## Keeping an IVIG Infusion Log

*Keeping a record of your IVIG infusions is quite easy. Basically, there are 4 pieces of information that you need to record with each infusion:*

- 1) **The Brand of IVIG:** The brand of IVIG is relatively easy to determine. The brand refers to either the company's name that makes the IVIG or the brand name that they use for their specific Immune Globulin. Usually, the company or brand name is listed on the label of the bottle or bag that the IVIG comes in. Your infusionist or nurse will also know the company's name or brand name since the prescription is usually written for a specific brand and it will also be listed in the written orders for the IVIG.
- 2) **The Amount of Immune Globulin:** Like the brand name or company name, the dose is listed on the label of the bottle or bag that the IVIG comes in. Your infusionist or nurse will also know the amount since the prescription is usually written for a specific amount and it will also be listed in the written orders for the Immune Globulin. The amount is usually written as the number of GRAMS of IVIG. In some instances, the amount may be listed as the volume of liquid in which the IVIG is dissolved, but even under these circumstances, the number of GRAMS will also be listed.
- 3) **The Date of the Infusion:** This is the date that you receive the actual infusion.
- 4) **The Lot of the Immune Globulin:** As mentioned above, plasma from thousands of donors is pooled together during the manufacturing process and each pool is given a "lot" number to keep track of it during the manufacturing process in order to identify the donors from which it was made, the time during which it was manufactured, and the results of the tests for quality control. Thus, the lot number allows precise identification of each IVIG preparation. Unfortunately, the lot number may not be on the bottle or bag hanging at the patient's side and may not be known to the infusionist or nurse since the written order or prescription for the IVIG does not specify lot number. Fortunately, the pharmacist who prepared the dose of Immune Globulin specific for the individual patient will usually have recorded the lot number while dispensing the IVIG. Thus, the patient or nurse can usually call the pharmacist and obtain the lot number. Should the pharmacist not be recording the lot number, then they should be asked to do so for all subsequent infusions.

## Immune Deficiency Diseases

The body's immune system is composed of dozens of different components, all working together to recognize foreign materials (also known as antigens) and react against them. In some instances the foreign material is a microbial invader such as a bacteria or virus that can cause infection, in other instances the foreign material is pollen from a plant that can cause an allergy such as hay fever, and in other instances the foreign material is a transplanted organ, such as a kidney, from another individual.

A number of disorders or diseases can affect the immune system and cause immune system diseases. Some of these diseases are characterized by a failure of the body's immune system to recognize or react against foreign material, termed immune deficiency diseases. Other diseases are characterized by the body's immune system inappropriately recognizing its own tissues as foreign and inadvertently reacting

against itself termed autoimmune diseases.

Immunoglobulins are one of the most important constituents of the immune system. Immunoglobulins (also known as antibodies) are large protein molecules that are folded and shaped in three dimensions to fit over foreign materials or antigens such as bacteria and viruses. Just as a key has serrations that vary from key to key and only allow any given key to fit one lock, each immunoglobulin molecule only fits over one foreign material. Thus, there are immuno-globulin molecules that fit perfectly with the tetanus bacteria but do not fit very well with polio virus or other microbes and other immunoglobulin molecules that fit perfectly with polio virus but not with tetanus or any other microbes. In fact, there are thousands upon thousands of different immunoglobulin molecules, each of which fits perfectly with one of the thousands of different microbes that are capa-

ble of causing infections in man.

There are a number of immune deficiency diseases in which there is a deficiency in the patient's ability to produce normal amounts of immunoglobulins. In some of these disorders, the defect is intrinsic to, or lies within, the cells that produce immunoglobulin (Primary Immunodeficiency Diseases). Examples of some of the Primary Immunodeficiency Diseases that may be treated with Immune Globulin include X-linked Agammaglobulinemia, Common Variable Immunodeficiency, X-linked Hyper IgM syndrome, Ataxia Telangiectasia and Severe Combined Immunodeficiency. In other disorders the defect in the Immune Globulin producing cells is secondary to another illness (Secondary Immunodeficiency Diseases). Examples of some of the Secondary Immunodeficiency Diseases that may be treated with Immune Globulin include Pediatric AIDS and Chronic Lymphocytic Leukemia.

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## Therapy with Intravenous Immune Globulin

Many of these immune deficiency diseases can be treated very successfully with IVIG replacement therapy. The intravenous Immune Globulin used to treat patients with immune deficiency diseases is made from the Immunoglobulins found in blood plasma of normal individuals. Plasma is removed from normal healthy donors and the Immune Globulin purified through a series of processes that remove the Immune Globulin from the hundreds of other proteins that are found in plasma. What is left at the end is a highly purified immunoglobulin preparation that has only trace (<1%) amounts of all the other plasma proteins.

Since the Immune Globulin is

purified from blood plasma, a number of steps are taken to insure that the IVIG is as free as possible from infectious agents; agents that might have been present in the donor to begin with or that might have contaminated the IVIG during its manufacture and purification. To begin with, the donors are screened to insure that they do not carry any infections that could be transmitted by blood plasma, such as the viruses that cause hepatitis or the virus that causes AIDS. This is accomplished by testing directly for these viruses in the donors. In addition, as a double check, donors are also tested to see if they have any evidence of hidden liver infection that might be caused by hepatitis. Donated plasma

is kept in inventory and is not used in manufacturing until the donor returns and gives another virus negative donation within a 2 month period of the first donation. In addition to screening donors for evidence of infections that could be transmitted through plasma, the purification process by which the immunoglobulin is separated from all the other plasma proteins also kills or removes some viruses as well. Finally, specific chemical processes that destroy viruses are also incorporated into the manufacturing process as yet another safety measure.

During the manufacturing process, the plasma from individual donors is combined, or pooled

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together. This accomplishes two goals. First, it increases the chance that a wide variety of immunoglobulin molecules capable of combining with a wide variety of infectious microorganisms are present in the final IVIG product, thus increasing the likelihood that it will contain the proper immunoglobulins to protect against

different infections. Second, it allows for a safer and more reliable manufacturing process. Each pool of Immune Globulin is given an identification number, or "lot" number to allow it to be monitored and followed during the manufacturing and distribution processes.

In most instances the purified Immune Globulin is infused directly into the patient's blood stream through an intravenous (IV) infusion. In the usual case, the immunoglobulin replacement lasts approximately one month in the patient and thus may only need to be given once a month.

***For more information contact:***

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