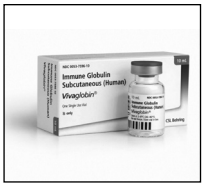
Vivaglobin®
Immune Globulin Subcutaneous (Human)

[Pronounced VEE-vah-glow-bin]



CSL Behring
Information for patients

This summary contains important information you need to know about Vivaglobin® for treating primary immunodeficiency (also known by its abbreviation, "PID"). *Please read it carefully before you start your treatment.* This summary is based on information given to your doctor but does not include all available information about Vivaglobin®. The summary is not meant to take the place of your doctor's instructions and should be used only after you have received instructions from your doctor. You should discuss any questions about treatment with Vivaglobin® with your doctor.

What is Vivaglobin®?

Vivaglobin® is a highly purified product, called an immune globulin, made from human plasma. Vivaglobin® contains the antibody immunoglobulin G (IgG), which is found in the blood of healthy individuals to help combat germs, such as bacteria and viruses. Because it helps the body rid itself of these bacteria and viruses, IgG is important in helping the body fight infection.

Vivaglobin® also contains the following inactive ingredients: 2.25% glycine, 0.3% sodium chloride, and water for injection.

What is Vivaglobin® used for?

Vivaglobin® is a prescription medication used to treat patients with primary immunodeficiency.

Vivaglobin® is supplied as a sterile liquid in single-use vials and is given by infusion subcutaneously (under the skin). **Do not administer Vivaglobin® into a blood vessel (vein or artery) as there is no safety information in patients supporting this route of administration.**

For treatment to be effective, you must carefully follow your doctor's instructions regarding your dose and treatment schedule for Vivaglobin®.

How does Vivaglobin® work?

Vivaglobin® treats primary immunodeficiency, a condition in which a person's natural defense system – or immune system – does not function properly.

Normally, our immune system helps protect us against infections by recognizing potentially harmful bacteria and viruses that enter our body every day. In response, the immune system produces special proteins called antibodies that fight these foreign invaders. However, when our immune system is not working properly, it is unable to produce these valuable antibodies, leaving us more vulnerable to infection and illness.

Vivaglobin® is known as antibody replacement therapy, because it replaces the missing and much-needed IgG antibodies in people who have low levels of this infection-fighting protein. By replacing these important antibodies, Vivaglobin® helps make people with PID better able to avoid infections and fight them when they do occur.

Who should <u>NOT</u> take Vivaglobin®?

People who have a history of allergic reactions to immunoglobulins or have a condition known as selective IgA deficiency should not use Vivaglobin®. Tell your doctor if you have ever had an allergic reaction due to either of these conditions. If a serious allergic reaction occurs at any time, stop the Vivaglobin® treatment and contact your doctor or an emergency medical professional immediately.

Because clinical studies with pregnant women have not been conducted, if you are pregnant or think you may be pregnant, discuss with your doctor whether Vivaglobin® is clearly needed. Please also consult your doctor about the use of this product if you are a nursing mother.

What are possible side effects of Vivaglobin®?

In clinical studies, Vivaglobin® has been shown to be safe and well tolerated in both adults and children. As with any medication, side effects may accompany treatment.

The frequency of side effects was based on a review of over 5,900 injections given during the clinical trials. The most frequently reported side effect was injection site reaction, which generally consisted of mild or moderate swelling, redness, and itching at the site of injection. In clinical trials, these reactions tended to decrease substantially over time. Please contact your healthcare provider if you would like more information on managing these reactions.

Other side effects may include:

- Headache
- Gastrointestinal disorder
- Fever
- Nausea
- Sore throat
- Rash
- Allergic reaction
- Increased cough
- Pain
- Diarrhea

If you are concerned about these or any other side effects, please talk to your healthcare provider.

What additional important information do I need to know about Vivaglobin®?

Immune Globulin Subcutaneous (Human) Vivaglobin® is made from the plasma portion of human blood. All plasma used to produce Vivaglobin® is collected in a manner that meets or exceeds U.S. Food and Drug Administration requirements. For your safety, we maintain stringent controls over plasma collection and processing every step of the way. Because Vivaglobin® is made from plasma, as are all immune globulins, the risk of transmitting infectious agents, including viruses, and theoretically, the Creutzfeldt-Jakob Disease (CJD) agent, cannot be completely eliminated. However, the risk that Vivaglobin® will transmit diseases is reduced by carefully screening plasma donors for prior exposure to certain viruses and by testing plasma for evidence of potentially harmful viruses. Only plasma that passed virus-screening is used for production of Vivaglobin®.

During the manufacture of Vivaglobin®, specific viral clearance methods further decrease the chance of disease transmission. The main virus reduction step of the Vivaglobin® manufacturing process is a pasteurization technique, which involves heating the product at 140°F (60°C) for 10 hours. Additional purification procedures used in the manufacture of Vivaglobin® further reduce the risk of disease. As with all products manufactured from human plasma, however, the risk of transmitting infectious agents cannot completely be eliminated. However, during clinical trials, no cases of infection due to hepatitis A, B, or C virus, parvovirus B19, or HIV were reported with the use of Vivaglobin®. If you believe that you have contracted an infection that was possibly transmitted by Vivaglobin®, you should report this to your doctor or healthcare provider.

What medications should I avoid while taking Vivaglobin®?

Vivaglobin® can impair the efficacy of certain virus vaccines, such as measles, mumps and rubella (also known by its abbreviation "MMR"). Inform the immunizing physician of recent treatment with Vivaglobin® so appropriate precautions can be taken.

Other products must not be mixed with the Vivaglobin® solution.

How do I store Vivaglobin®?

Vivaglobin® is supplied in single-use vials. It contains no preservatives, so any unused portion should be discarded immediately after use. When stored in the refrigerator at 36° to 46°F (2° to 8°C) Vivaglobin® can be used until the expiration date on its label. Do not use after the expiration date. *Do not freeze Vivaglobin®*. Keep the vial in its box during storage. Keep Vivaglobin® and all other medications out of the reach of children.

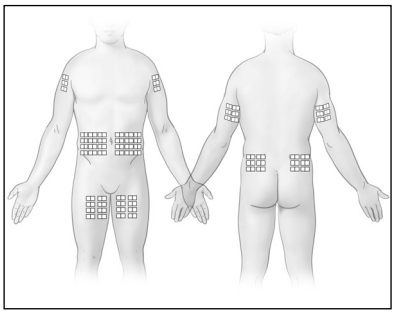
How do I use Vivaglobin®?

Vivaglobin® is infused subcutaneously (under the skin). Do not administer it into a blood vessel (vein or artery).

Your doctor will determine the appropriate dose for your treatment.

Your doctor or healthcare provider will teach you the proper techniques for administering Vivaglobin®. **Only after such instruction should you follow the instructions below.**

Preparing for your treatment



The following areas are recommended for subcutaneous infusion of Vivaglobin®:

- Abdomen
- Thighs
- Upper arms
- Hip

For proper selection of infusion site, please consult your doctor or healthcare provider.

Instructions for administration

The following instructions are intended only as a guide. Before administering Vivaglobin® Immune Globulin Subcutaneous (Human) you should be under the care of a doctor and should have received proper training on proper preparation and administration from a licensed healthcare provider.

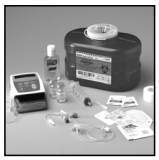


Fig. 1

1. Prior to use, allow the vial(s) of Vivaglobin® to reach room temperature, 68° to 77°F (20° to 25°C). On a clean, flat surface, such as a table, assemble all the supplies you will need for your treatment, including Vivaglobin® vials, treatment diary/logbook, an infusion pump, administration tubing, subcutaneous needle or catheter, Y-site connection tubing (if needed), alcohol wipes, antiseptic skin preps, syringe(s), needle(s), gauze or transparent dressing, tape and a sharps disposal container. Your healthcare provider can help you to identify a complete list of supplies. Discuss with your healthcare provider whether you should use gloves when preparing Vivaglobin® for infusion. (Fig. 1)


Fig. 2

2. There are several different types of ambulatory infusion pumps that may be used to administer Vivaglobin®. Your healthcare provider will help you to determine which type of pump is appropriate for you. Follow the pump manufacturer's instructions for preparing the infusion pump and priming the administration tubing. Set the rate of infusion on the pump as instructed by your healthcare provider.


Fig. 3

3. Before preparing Vivaglobin® for infusion, thoroughly wash and dry your hands. (Fig. 2)


Fig. 4

4. Before each infusion, be sure to visually inspect each vial of Vivaglobin® for discoloration and for particles in the solution by gently swirling each vial (do **not** shake the vial). Vivaglobin® should be a clear solution that can vary from colorless to light brown. If the solution in a vial is cloudy or contains particles, or if the protective cap is missing, do not use it. Check the expiration date on each vial of Vivaglobin®. Do not use beyond the expiration date. (Fig. 3)


Fig. 5

5. Remove the protective cap from each vial of Vivaglobin®. Next, cleanse the top of each vial stopper with an alcohol wipe, and allow the top of the vial to dry. (Figs. 4 and 5)


Fig. 6

6. Using aseptic technique as instructed by your healthcare provider, attach a needle to the syringe tip. (Fig. 6)


Fig. 7

7. Pulling back on the syringe plunger, draw back a volume of air into the syringe that is equal to the volume of Vivaglobin® that will be withdrawn. With the Vivaglobin® vial placed on a flat surface, insert the needle into the center of the vial stopper. Then inject the air into the vial. Next, leaving the syringe and needle in the vial, carefully invert the vial as shown in the illustration. Withdraw the Vivaglobin® solution into the syringe and remove the filled syringe from the vial. Remove the needle from the syringe filled with Vivaglobin® and discard the needle into a sharps disposal container. Repeat this step if multiple vials are required to achieve the prescribed dose of Vivaglobin®. (Fig. 7)

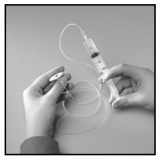


Fig. 8

8. Follow manufacturer's instructions for filling the infusion pump reservoir and priming the administration tubing and needle/catheter. "Priming" the administration tubing refers to the removal of the air from the tubing and needle/catheter that will be used to infuse Vivaglobin®. Priming may also be done by connecting the syringe filled with Vivaglobin® to the administration tubing and gently pushing on the syringe plunger to fill the tubing with Vivaglobin® until a drop is seen exiting the needle/catheter. (Fig. 8)

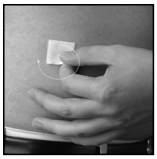


Fig. 9

9. Select an appropriate infusion site(s), depending on the amount required for your total Immune Globulin Subcutaneous (Human) Vivaglobin® dose and the instructions of your healthcare provider. Cleanse the site(s) with antiseptic skin prep(s) beginning in the center of the site and working outward in a circular motion. Allow site(s) to dry before proceeding to the next step. If your healthcare provider recommends that you administer Vivaglobin® using multiple sites, ensure that each site is at least two inches apart. (The maximum recommended infusion volume per infusion site is 15 mL). (Fig. 9)

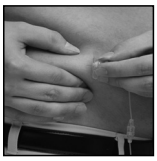


Fig. 10

10. Using two fingers, grasp the skin around the infusion site. As instructed by your healthcare provider, insert the needle directly into the subcutaneous tissue and **not** into a blood vessel. (Fig. 10)

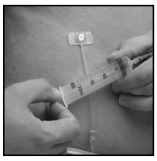


Fig. 11

11. After each needle is inserted into the tissue, you must test to make sure that a blood vessel has not been accidentally entered. This must be done prior to starting your infusion. To do this attach a sterile syringe to the end of the primed administration tubing, and gently pull back on the syringe plunger. Look to see if any blood is flowing back into the administration tubing. If you see any blood, remove and discard the needle and administration tubing. Then, repeat steps 8–11 using a new needle, administration tubing and a new infusion site. (Fig. 11)

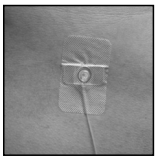


Fig. 12

12. Secure the needle by applying sterile gauze or transparent dressing over the site and tape in place. (Fig. 12)

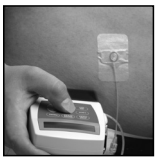


Fig. 13

13. Secure the administration tubing to the infusion pump following the manufacturer's instructions and turn on the pump. (Fig. 13)


Fig. 14

14. Once the infusion is complete, turn off the infusion pump. Remove the needle(s) from the infusion site(s) and discard any unused solution and administration equipment in accordance with biohazard procedures as recommended by your healthcare provider. Follow the manufacturer's instructions regarding care of the infusion pump after each use. (Fig. 14)


Fig. 15

15. On each Vivaglobin® vial, you will find a peel-off label with the product lot number and expiration date. Record the time, date, and exact dose of your infusion, then remove the labels and affix them to your treatment diary/logbook. Take this record of your treatment with you whenever you visit your physician. (Fig. 15)

These instructions are intended to serve as a guide for people who have already been instructed by a healthcare professional on the proper method of preparing and administering Vivaglobin®. If you have not received such training, please consult your healthcare provider before attempting to administer Vivaglobin®. If you experience any problems or need more information regarding your subcutaneous treatment, contact your healthcare provider.

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