

PRIMARY IMMUNODEFICIENCY (PI) ADMINISTRATION OPTIONS

Intravenous (IV) or Subcutaneous (SC) Which one is right for you?

GAMMAGARD LIQUID
[Immune Globulin
Infusion (Human)] 10%

Making the Appropriate Choice. In your discussion with your doctor on the method of IgG infusion, consider the following factors and check a box at the right to indicate whether SC or IV administration best accommodates that aspect of your life right now.

Lifestyle

- IV is administered every 3 or 4 weeks at a scheduled appointment, either at an infusion center (a hospital, clinic, or doctor's office) or in your home.^{1,3} Infusion times will vary, depending on dosing and patient tolerability.² IV
- SC can be administered by you or a caregiver, usually once a week at home. Infusion times and infusion sites will vary.² SC

Considerations for You or Your Caregiver

- Are you able to commit about half a day every 3 or 4 weeks to attend a scheduled IV appointment?
- Would you prefer to infuse SC at home on an established weekly schedule or IV every 3 or 4 weeks by appointment at an infusion center?
- Do you feel you could infuse SC on your own each week?

Confidence and Ability

- IV is administered to you by a healthcare professional through a single needle placed in a vein.^{1,3} IV
- SC can be administered by you through a small needle placed beneath your skin (may require multiple infusion sites), using an infusion pump.^{1,3} SC

Considerations for You or Your Caregiver

- Do you feel you can confidently insert one or more small needles in yourself, as required for SC administration?
- Would you be comfortable infusing SC by yourself without a doctor or nurse present?
- Do you have a responsible person at home who can seek immediate medical attention if you experience a serious side effect?
- Do you have any physical limitations that might interfere with your ability to infuse SC, such as arthritis in the fingers?
- Would you agree to be trained by your doctor or nurse before starting SC administration?

Physical Characteristics

- IV is infused into a vein, through a needle, at a single site.¹ IV
- SC is infused under your skin through a small needle, placed at body areas such as the abdomen, thighs, upper arms, or lower back (may require multiple infusion sites, not to exceed 8 sites).^{1,2,3} SC

Considerations for You or Your Caregiver

- Do doctors or nurses have trouble finding your veins for IV infusions?
- Do you have skin conditions (inflammation, irritation or infection) that would limit possible SC infusion sites?

Please see Indications and Detailed Important Risk Information on page 3 and accompanying full Prescribing Information, including Boxed Warning.

Environment

- IV is administered to you by a healthcare professional in your home or at an infusion center.^{1,3}
- SC can be administered by you at home, requiring you to keep supplies and an infusion pump on hand.³

IV
 SC

Considerations for You or Your Caregiver

- Do you have support at home to help you if you need it?
- Do you have a safe place to store supplies in your home, such as an open shelf in a closet or room in a cabinet or refrigerator?
- Is your home environment suitable to performing a weekly SC infusion?
- Will you need to take precautions because of small children in the home?
- Do you have pets that may interfere with the infusion?

Previous Treatment Experience

- Regardless of IV or SC administration, all IgG treatments have potential side effects; different treatments and routes of administration may have different risks and may cause different side effects.^{2,3} For IV administration, side effects may occur more frequently if you are receiving immune globulin for the first time, have switched brands or if there has been a long interval since the previous infusion.^{2,3} For subcutaneous administration, the proportion of patients who experience local side effects may be highest immediately following the switch from IV to SC treatment.²

IV
 SC

Considerations for You or Your Caregiver

- Have you ever been treated with either IV or SC IgG treatment in the past and had any problems?
- Which product were you treated with?
- Do you have a history of poor kidney function or failure, diabetes, lung problems, heart disease, or blood clots?

> Now that you have considered the above, consult with your doctor about whether IV or SC treatment would best fit your lifestyle.

References

1. Blaese RM, Winkelstein JA, eds. *Patient & Family Handbook for Primary Immunodeficiency Diseases*. Towson, MD: Immune Deficiency Foundation; 2007.
2. GAMMAGARD LIQUID [Immune Globulin Infusion (Human)] 10% [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.
3. Blaese RM, ed. *IDF Guide for Nurses on Immune Globulin Therapy for Primary Immunodeficiency Diseases*. Towson, MD: Immune Deficiency Foundation; 2007.

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GAMMAGARD LIQUID

[Immune Globulin Infusion (Human)] 10%

Indication

GAMMAGARD LIQUID is used to treat patients two years of age and older with primary immunodeficiency diseases (PI). There are many forms of PI. GAMMAGARD LIQUID contains antibodies collected from healthy people that replace the missing antibodies in PI patients.

Detailed Important Risk Information

Stop the infusion immediately and contact your healthcare provider or call emergency services if you have any of the following:

Symptoms of thrombosis (blood clots) that may include: pain and/or swelling of an arm or leg with warmth over the affected area, discoloration (redness) or lump in an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body.

Symptoms of a kidney problem that may include: reduced urination, sudden weight gain or swelling in your legs.

Symptoms of a serious allergic reaction that may include: hives, skin rash, itching, swelling in the mouth or throat, trouble breathing, wheezing, fainting or dizziness.

Other serious symptoms including: bad headache with nausea, vomiting, stiff neck, drowsiness, fever, sensitivity to light, painful eye movements; brown or red urine, fast heart rate, yellow skin or eyes; trouble breathing, blue lips or extremities; fever over 100°F.

Tell your healthcare provider if you have a history of thrombosis (blood clots), thrombotic events, poor kidney function or kidney failure.

Do not use GAMMAGARD LIQUID if you have a known history of a severe allergic reaction to immune globulin or other blood products. If you have such a history, discuss this with your healthcare provider to determine if GAMMAGARD LIQUID can be given to you. Tell your healthcare provider if you have a condition called selective (or severe) immunoglobulin A deficiency.

GAMMAGARD LIQUID is made from human blood. It may contain infectious agents that can cause disease e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD), and theoretically, the Creutzfeldt-Jakob disease agent. Patients should report any symptoms that concern them which might be caused by virus infections.

GAMMAGARD LIQUID can make vaccines (e.g., measles, mumps, rubella, or chicken pox vaccines) not work as well. It may also affect your blood test results. Before you get any vaccines or have your blood tested, tell your healthcare provider that you take GAMMAGARD LIQUID.

The following is a list of common side effects seen in clinical trials of GAMMAGARD LIQUID (for Primary Immunodeficiency):

IV administration: Headache, fatigue, fever, nausea, chills/shaking chills, pain in extremity, diarrhea, migraine, dizziness, vomiting, cough, hives, asthma, throat pain, rash, joint pain, muscle pain, swelling, itching, and cardiac murmur.

Subcutaneous administration: Infusion site reactions (i.e., mild or moderate pain, swelling, itching, redness, bruising, and/or warmth), headache, fatigue, increased heart rate, fever, upper abdominal pain, nausea, vomiting, asthma, increased blood pressure, diarrhea, ear pain, canker sores, migraine, sore throat, and pain in extremity.

Although it is possible to receive IV infusions at home, they are more often given in a hospital or infusion center by a nurse. Whenever giving yourself treatments at home, you should have another responsible person present to help treat side effects or get help should a serious adverse reaction occur. Ask your healthcare provider whether you should have rescue medications, such as antihistamines or epinephrine.

Please see the accompanying full Prescribing Information, including the Patient Product Information.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.