SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) ADMINISTRATION

Quick Reference Guide

brought to you by

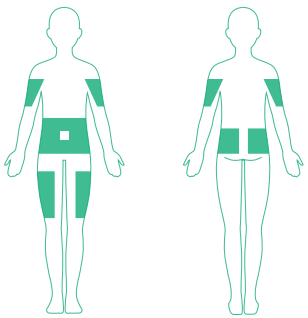
Xembify®
(immune globulin subcutaneous human-klhw) 20%

Please see Important Safety Information throughout and refer to accompanying full Prescribing Information for XEMBIFY.

GETTING STARTED WITH SCIG

The administration of SCIG for primary humoral immunodeficiency diseases (PIDD) can vary from one patient to another based on each individual's needs. You can use the tips throughout this guide to help set up your patient for the most comfortable and successful administration.

Select an administration site[1,2]



FRONT BACK

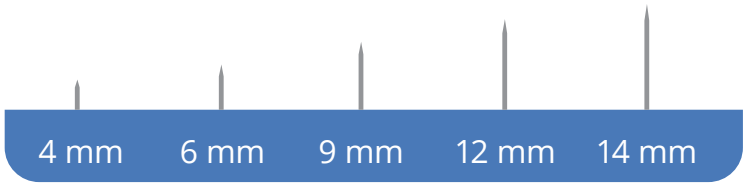
First, select an appropriate site on your patient's body to administer SCIG. Infuse SCIG in the abdomen, thigh, upper arms, sides, back, and/or lateral hip. It is recommended that you rotate infusion sites throughout your patient's treatment, avoiding bony areas, scars, areas of inflammation, superficial infection, or blood vessels.

TIPS[1-5]

- Recommend that the patient use the restroom before needle insertion
- Administer SCIG at room temperature
- Always use aseptic technique
- "Dry prime" the tubing and needle setup to the needle hub
- If medication is on the tip of the needle, allow needle to dry prior to insertion to avoid possible skin irritation
- Pinch at least 1 inch of skin and insert the SCIG needle at a 90-degree angle; secure to the skin to avoid movement
- Avoid inserting the SCIG needle into bony areas, scars, areas of inflammation, superficial infection, or blood vessels
- Confirm needle placement after insertion to ensure it is not in a blood vessel
- Keep infusion sites 2 inches away from umbilicus and at least 2 inches away from other infusion sites
- For patients who are afraid of needles, comfort measures may include: lidocaine and prilocaine, The Buzzy®, or ice before needle insertion

Select the appropriate needle gauge and length[1,4]

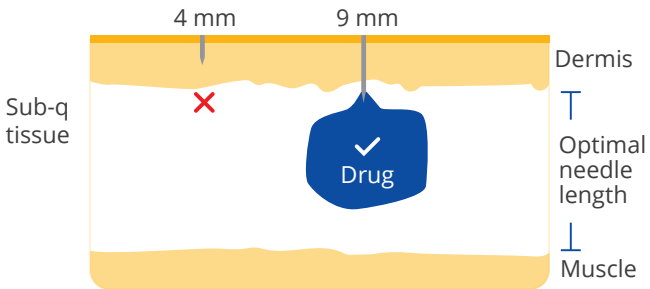
SCIG can be administered with various gauge needles. Choose the most appropriate needle diameter to accommodate the volume of IG infused, based upon the individual needs of your patient.



Not actual sizes.

The length of the needle you choose is dependent on the size and/or age of the patient. Generally, the following sizes are recommended:

- **4 mm:** Infants
- **6 mm:** Children ages ≤9 years and patients who have extremely low body fat
- **9 mm/12 mm:** Children ages >9 years and most adults
- **14 mm:** Adults who are larger than average in size



TIPS[1]

- Longer needles may help reduce site irritation
- More needles allow faster infusions with less discomfort (2 vs 3 sites)*
- Slowing an infusion can reduce site discomfort

IG, immune globulin; sub-q, subcutaneous.

*XEMBIFY may be infused using up to 6 infusion sites.[2] In a clinical trial, most patients used 4 infusion sites.[6]

MONITORING[3]

Below are common adverse site reactions with interventions to reduce patient discomfort due to these reactions:

Local itching

- Ensure dry needle insertion
- Apply a cold compress
- Use an over-the-counter topical steroid
- Use a longer needle
- Decrease volume infused per site

Redness

- Apply a cold compress
- Change needle tape or adhesive

Burning

- Pause infusion for 5 to 10 minutes
- Slow the infusion rate
- Apply a cold compress
- Consider changing the infusion site or volume infused per site, depending on severity
- Assess needle placement and consider a shorter needle
- Confirm if antiseptic used for skin prep is leading to burning; alcohol can sting if skin isn't dry

Swelling

- Some swelling is expected during SCIG administration
- Apply a warm compress for 5 to 10 minutes
- Use a heating pad on a low setting
- Give the patient a gentle massage at the affected site
- Consider changing the infusion site or volume infused per site

Urticaria/hives

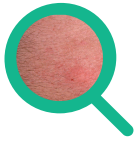
- Stop infusion
- Contact prescriber for instructions to determine if infusion should continue
- Use an antihistamine if needed

Discomfort

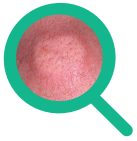
- Slow infusion
- If the pain is intolerable, the needle may be in the muscle. Change the infusion site
- Apply a warm compress
- Give the patient a gentle massage at the affected site
- Consider over-the-counter analgesics, although they are usually unnecessary

Rash

- Determine if the rash is local or systemic. If systemic, stop SCIG administration
- Contact prescriber for instructions to determine if infusion should continue
- Determine if rash could be due to a tape or latex allergy or sensitivity



Mild infusion-site reaction



Moderate infusion-site reaction

TIPS[1-3]

- Educate the patient or caregiver that local reactions are common and expected. Most are mild and diminish as the drug is absorbed over 24 to 72 hours
- Assess size of swelling. Is it a mosquito-bite, raised wheel, or quarter size? Swelling should be consistent with volume being infused and the amount of subcutaneous tissue
- Thinner patients may have a more pronounced, raised area; decrease volume per site as necessary
- Local site reactions are more common when starting SCIG and include pain, redness, puffiness, bruising, nodules, itching, firmness, scabbing, and swelling
- Systemic side effects may also occur, including headache, nausea, vomiting, fatigue, cough, and diarrhea
- Oral hydration may decrease systemic adverse reactions. Unless instructed otherwise by a physician, remind patients to drink water the day before, day of, and day after SCIG administration

Indication

XEMBIFY® (immune globulin subcutaneous human–klhw) is a 20% immune globulin indicated for treatment of primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older. XEMBIFY is for subcutaneous administration only.

Important Safety Information

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin products, including XEMBIFY. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors**
- **For patients at risk of thrombosis, administer XEMBIFY at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity**

Contraindications

XEMBIFY is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. It is contraindicated in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity.

Warnings and Precautions

Aseptic meningitis syndrome (AMS). AMS may occur with human immune globulin treatment, including XEMBIFY. Conduct a thorough neurological exam on patients exhibiting signs and symptoms to rule out other causes of meningitis. Discontinuation of treatment has resulted in remission within several days without sequelae.

Thrombosis. Thrombosis may occur following treatment with immune globulin products, including XEMBIFY. Thrombosis may occur in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

Hypersensitivity. Severe hypersensitivity reactions may occur with immune globulin products, including XEMBIFY. In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. XEMBIFY contains IgA. Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

Renal dysfunction/failure. Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with use of human immune globulin products, especially those containing sucrose. XEMBIFY does not contain sucrose. Ensure patients are not volume-depleted prior to starting infusion. In patients at risk due to preexisting renal insufficiency or predisposition to acute renal failure, assess renal function prior to the initial infusion of XEMBIFY and again at appropriate intervals thereafter. If renal function deteriorates, consider discontinuation.

Hemolysis. XEMBIFY may contain blood group antibodies that may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for clinical signs and symptoms of hemolysis. If signs and symptoms are present after infusion, perform confirmatory lab testing.

Transfusion-related acute lung injury (TRALI). Noncardiogenic pulmonary edema may occur in patients following treatment with immune globulin products, including XEMBIFY. Monitor patients for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of antineutrophil and anti-HLA antibodies in both the product and patient serum. TRALI may be managed using oxygen therapy with adequate ventilatory support.

Transmissible infectious agents. Because XEMBIFY is made from human blood, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt- Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. No cases of transmission of viral diseases, vCJD, or CJD have ever been associated with the use of XEMBIFY.

Interference with lab tests. After infusion of XEMBIFY, passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation.

Adverse Reactions

The most common adverse reactions in ≥ 5% of subjects in the clinical trial were local adverse reactions, including infusion-site erythema (redness), infusion-site pain, infusion-site swelling (puffiness), infusion-site bruising, infusion-site nodule, infusion-site pruritus (itching), infusion-site induration (firmness), infusion-site scab, infusion-site edema, and systemic reactions including cough and diarrhea.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (eg, measles, mumps, rubella, and varicella).

Please see accompanying full Prescribing Information for XEMBIFY.

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ADDITIONAL CONSIDERATIONS FOR ADMINISTERING IG PRODUCTS

Premedication may not be necessary[1]

Connect the patient and caregiver to PIDD patient support groups[3]

An infusion logbook can enhance provider and patient communication and treatment plan[3]

Educate the patient and caregiver on disease state and treatment to help guide plan of care[3]

To learn more about SCIG administration, visit **www.XEMBIFY.com/en/hcp/dosing** or **scan this QR code**

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Maximum support

Eligible XEMBIFY patients can pay as little as ZERO copay!

XEMBIFY.com

1-844-MYXEMBIFY
(1-844-699-3624)

References: 1. Immunoglobulin National Society. *Immunoglobulin Therapy Standards of Practice.* 3.2 ed. Ig Society, Inc.; 2024. **2.** XEMBIFY Prescribing Information. Grifols. July, 2024. **3.** Immune Deficiency Foundation. *IDF Guide for Nurses: Immunoglobulin Therapy for Primary Immunodeficiency Diseases*. 4th ed. 2016. **4.** KORU Medical Systems. Resource Hub. Accessed September 10, 2024. https://www.korumedical.com/resource-center **5.** McFalls K. Decreasing infusion anxiety. *IG Living*. June-July 2011; 42-43. **6.** Sleasman JW, Lumry WR, Hussain I, et al. Immune globulin subcutaneous, human - klhw 20% for primary humoral immunodeficiency: an open-label, phase III study. *Immunotherapy.* 2019;11(16):1371-1386.

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GRIFOLS

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