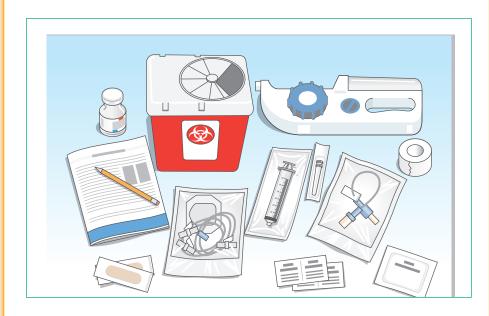


# Your XEMBIFY Quick Reference Infusion Guide

Here are the key steps to follow when infusing XEMBIFY.

# **Collect your supplies**



- Vial(s) of XEMBIFY •
- Syringe
- Needle sets
- Infusion tubing
- Alcohol wipes
- Gauze

- Transparent dressing and tape
- Bandages
- Infusion pump
- Infusion Log Book
- Sharps container

# **Keep in mind**

- Always infuse XEMBIFY at room temperature
- Do not use the XEMBIFY vial if:
  - » Liquid is cloudy or has particles
  - » Vial shows any sign of tampering
- Be sure to choose sites that are:
  - » 2 inches apart in the abdomen, thigh, upper arm, sides, back, or hip
  - » 2 inches away from the belly button
  - » Different from your last infusion
- Avoid bony areas, visible blood vessels, scars, and any areas of inflammation (irritation) or infection
- Do not use more than 6 infusion sites at the same time
- Never infuse XEMBIFY into a blood vessel
- Stay hydrated throughout the infusion

# **Infusion Steps**



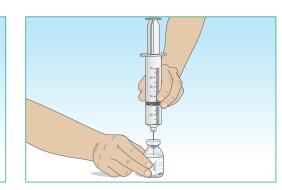
#### 1. Clean surface and hands

Disinfect surface to be used for your infusion. Allow the vial(s) of XEMBIFY to reach room temperature. Set up all your supplies. Wash and dry your hands thoroughly.



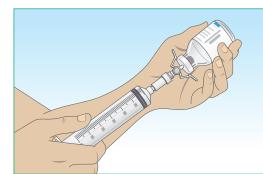
#### 2. Inspect vial of **XEMBIFY**

Check for correct name and expiration date. Make sure liquid inside is clear. Remove seal and protective cap. Clean rubber stopper with an alcohol wipe and allow to air dry.



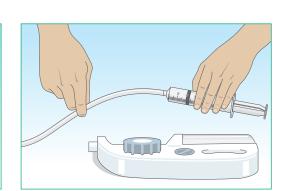
# **3A. Draw XEMBIFY** using needle

*If using needle*, attach it to the syringe tip and remove the cap. Pull the plunger back to desired level and inject air into the vial. Turn vial and syringe upside down. Place needle below fluid level. Withdraw XEMBIFY.



## 3B. Draw using transfer device

If using transfer device, uncap and attach to the syringe. Place vial on a flat surface and insert transfer device into top of the vial. Turn vial and syringe upside down and withdraw XEMBIFY.



## 4. Prime the infusion tubing

Follow the pump manufacturer's instructions to attach the infusion tubing and needle set to the syringe. Prime the tubing by filling it with XEMBIFY. Make sure the needle remains dry while priming.



## 5. Prepare infusion site(s)

Select one or more infusion sites as directed by your healthcare provider. Prepare the site(s) by cleaning with an which is the innermost alcohol wipe.



#### 6. Insert needle(s) into sites

Grasp the skin between 2 fingers and insert the needle into the subcutaneous tissue, layer of your skin.



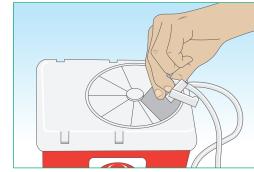
#### 7. Make sure needle is not in blood vessel

If you see blood when pulling back on the plunger, remove and discard the needle and tubing. Repeat steps 5-7 using a new needle, tubing, and a new infusion site. Secure needle with adhesive dressing. Repeat for other sites as needed.



## 8. Load syringe and begin infusion

Follow pump instructions to load the syringe and start the infusion. Infusion is complete when the syringe is empty. Use XEMBIFY within 2 hours of drawing up in a syringe to avoid the potential formation of particles caused by siliconized syringes.



# 9. Turn off pump and end infusion

Wash hands again. Follow instructions to turn off the pump. Undo and discard dressing/tape. Gently remove inserted needle(s). Discard used needles and tubing in a sharps container. Record your infusion in the Log Book.

Record each infusion in your Log Book, and remember to share it with your healthcare professional at your next visit.



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

#### What is XEMBIFY®?

XEMBIFY® (immune globulin subcutaneous human–klhw) is a 20% immune globulin used in the 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 (formation of blood clots within blood vessels) may occur with immune globulin products, including XEMBIFY. Before you take XEMBIFY, talk to your doctor if you:
  - Are older
  - Are sedentary (need to lie down or sit down) for long periods of time
  - Are taking estrogen-containing medicines (birth control pills, hormone replacement therapy)
  - Have a permanent intravenous (IV) catheter
  - Have hyperviscosity of the blood (diseases such as multiple myeloma or other causes of elevated proteins in the blood)
  - Have cardiovascular (heart) problems or previous history of stroke
- Thrombosis may occur even if you don't have any risk factors
- If you are at risk of thrombosis, your doctor may prescribe XEMBIFY at the minimum dose and infusion rate. Make sure you drink plenty of fluid before taking XEMBIFY. Make sure your doctor is checking you regularly for signs and symptoms of thrombosis and is checking your blood viscosity if you are at risk of hyperviscosity

#### Who should not use XEMBIFY?

• XEMBIFY should not be used if you have had a severe allergic reaction to human immune globulin, or if you have been told by a doctor that you are IgA deficient and have developed antibodies to IgA and hypersensitivity after exposure to a previous plasma product

#### What are possible serious side effects of XEMBIFY?

• Aseptic meningitis syndrome (AMS). Aseptic meningitis is a non-infectious inflammation of the membranes that cover the brain. It causes a severe headache syndrome, which may occur with human immune globulin treatment, including XEMBIFY. If you are showing signs and symptoms of AMS, your doctor may conduct a thorough neurological evaluation including spinal tap (sampling fluid which surrounds the spinal cord) to rule out other causes of meningitis. Stopping human immune globulin treatment has resulted in the end of signs and symptoms within several days. Treatment may include analgesics (pain medicines) and/or a special procedure known as a "blood patch" to stop headache

- **Hypersensitivity.** Severe allergic reactions may occur with immune globulin products, including XEMBIFY. If you have a severe allergic reaction, stop the infusion immediately and get medical attention. XEMBIFY contains IgA. If you have known antibodies to IgA, you may have a greater risk of developing potentially severe allergic reactions
- Kidney problems or failure. Kidney problems or failure may occur with use of human immune globulin products, especially those containing sucrose (sugar). XEMBIFY does not contain sucrose. If you have kidney disease or diabetes with kidney involvement, your doctor should perform a blood test to assess your hydration level and kidney function before beginning immune globulin treatment and at appropriate intervals thereafter. If your doctor determines that kidney function is worsening, they may discontinue treatment
- **Hemolysis.** Your doctor should monitor you for symptoms of hemolysis (destruction of red blood cells causing anemia, or low red blood cell count). If your doctor suspects hemolysis, they should perform additional tests to confirm
- **Transfusion-related acute lung injury (TRALI).** TRALI is a rare but serious syndrome characterized by sudden acute respiratory distress following transfusion. If your doctor suspects TRALI, they will monitor you for any other lung issues. TRALI may be managed with oxygen therapy
- **Transmissible infectious agents.** Because XEMBIFY is made from human blood, it may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. No cases of transmission of viral diseases or CJD have been associated with the use of XEMBIFY
- Interference with lab tests. Because XEMBIFY contains a variety of antibodies, blood tests to determine antibody levels may be falsely elevated. Be sure to tell your doctor or lab technician that you are using XEMBIFY

#### What are other possible side effects of XEMBIFY?

- In clinical studies of XEMBIFY, some patients experienced local side effects (at the injection site) including pain, redness, puffiness, bruising, nodules, itching, firmness, scabbing and swelling at the site on the skin where the injection occurred. Some patients experienced non-injection-site side effects including cough and diarrhea
- Use of XEMBIFY may interfere with the immune response to virus vaccines, such as vaccines for measles, mumps, rubella and varicella. Tell your doctor you are taking XEMBIFY before getting vaccinations

Please see accompanying full Prescribing Information for XEMBIFY.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

To learn more about XEMBIFY or Xembify Connexions, visit XEMBIFY.com or call 1-844-MYXEMBIFY (1-844-699-3624).



