



For patients starting XEMBIFY

A GREAT START STARTS HERE

Explore the comprehensive
support and services
available to you



Please see Important Safety Information on pages 10 and 11, and refer to accompanying full Prescribing Information for XEMBIFY.

GRIFOLS

XEMBIFY RESOURCES PROVIDE STRONG SUPPORT RIGHT FROM THE START

When you start on XEMBIFY, you'll have access to helpful tools and information to get the most out of your treatment.

The following materials are included in your **XEMBIFY Starter Kit**.



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Living with PIDD Brochure

Learn about living with PIDD (primary humoral immunodeficiency disease) and how to begin therapy with XEMBIFY.



LIVING WITH PIDD*

Managing your symptoms with XEMBIFY



Please see Important Safety Information on pages 18 and 19, and refer to accompanying full Prescribing Information for XEMBIFY.

*PIDD=primary humoral immunodeficiency disease.

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Symptoms of PIDD?

Symptoms of PIDD vary from person to person. If someone has any of the symptoms below, encourage them to see a doctor. Early detection of PIDD can help prevent long-term complications.

Symptoms^{1,2}

- Infections that occur more frequently and are more severe, longer lasting, and more difficult to cure when compared to people with healthy immune systems, such as sinus infections
- Getting sick with infections that a healthy immune system would normally be able to fight off, such as common colds
- Autoimmune problems, such as autoimmune lung or skin disease, which happen when the immune system attacks the body's own organs and tissues instead of attacking germs and disease-causing materials

What causes PIDD?

Overview of the immune system

The immune system is an incredible collection of cells, proteins, tissues, and organs that defends against a wide variety of germs every day.³

How does it work?



The body's immune system makes special proteins called antibodies



When the body detects a threat, like a germ that can make you sick, it responds by making these antibodies



Antibodies defend the body by attaching to the threat and signaling the body to destroy the germ

The immune system in people with PIDD¹


Usually, the immune system does a great job protecting the body from threats. But in people who have PIDD, the immune system doesn't work properly. In some cases, the immune system may not work at all. As a result, germs are more likely to get through your body's defenses.

4 Please see Important Safety Information on pages 18 and 19, and refer to accompanying full Prescribing Information for XEMBIFY.

5

Quick Reference Infusion Guide


Follow the steps, illustrated on this large-format mat, to prepare and administer your infusions. Its water-resistant surface can be cleaned easily for repeated use.



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
- Disinfecting wipes
- Gauze
- Transparent dressing and tape
- Bandages
- Infusion pump
- Infusion log book
- Sharps container


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 disinfecting 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, uncip 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
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 alcohol wipe.




6. Insert needle(s)
into site
Grasp the skin between 2 fingers and insert the needle. Secure needle with adhesive dressing. Repeat for other sites as needed.



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.



8. Load syringe and begin infusion
Follow the pump manufacturer's instructions to load the syringe and start the infusion. The infusion is complete when the syringe is empty.



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 needles. Discard used needles and tubing in a sharps container. Record your infusion in the log book.

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 disinfecting wipe and allow to air dry.

8. Load syringe and begin infusion

Follow the pump manufacturer's instructions to load the syringe and start the infusion. The infusion is complete when the syringe is empty.

GRIFOLS

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Infusion Log Book

Track your infusions and how they felt, and remember to share your Infusion Log Book with your healthcare provider at your next visit.



Notes on my therapy

Date of infusion: / / Dose infused: Check one: ☐ grams (g) ☐ milliliters (mL)

Time infusion started: Time infusion ended:

Needle size: Infusion rate:



Number of sites and areas infused this week (please mark with an X):

Peel "lot number and expiration date" label from XEMBIFY vial and affix here.

Peel "lot number and expiration date" label from XEMBIFY vial and affix here.

Peel "lot number and expiration date" label from XEMBIFY vial and affix here.

Lot # Expiration date

Lot # Expiration date

Lot # Expiration date

Week

Notes on my therapy

Medications I have taken:

BEFORE infusion	DURING infusion	AFTER infusion

Side effects I experienced:
Infusion site reactions such as redness, swelling, pain, or itching. Note the time they began and any measures you took to address them.

Overall reactions such as headache, flu-like symptoms, fatigue, fever, and pain or discomfort. Note the time they began and any measures you took to address them.

Questions for my doctor or nurse:

6

Please see Important Safety Information inside, and refer to accompanying Full Prescribing Information for XEMBIFY.



Self-Administration Resources

Use the Self-Administration Video and other resources provided in the XEMBIFY Starter Kit to make every infusion as convenient and comfortable as possible.

The kit includes a Buzzy® Mini Personal, which uses a patented combination of cold and vibration to reduce the pain of injections.

The kit also includes a set of DistrACTION® cards, hand sanitizer, and a pen.



To watch the Self-Administration Video, scan the QR code to the right, view it on the USB, or visit XEMBIFYinfusionvideo.com.

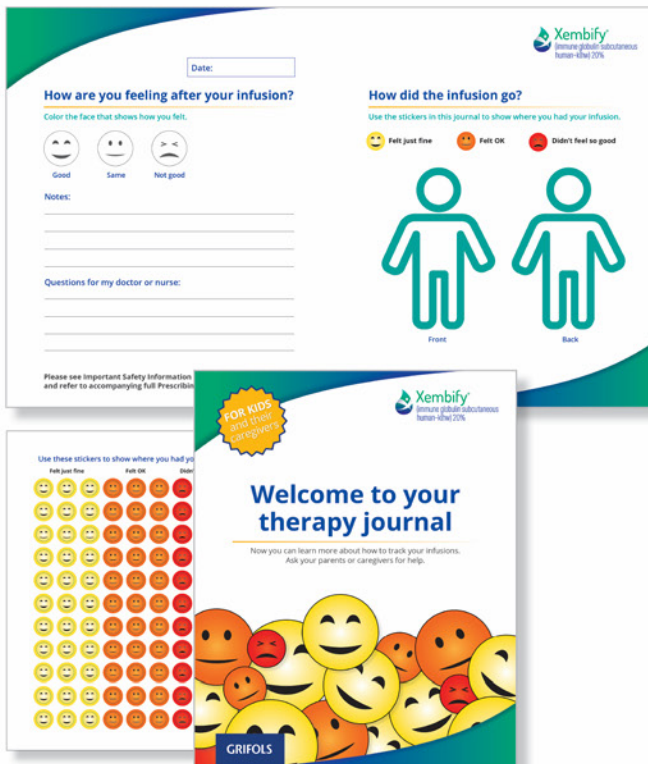


Buzzy® is a registered trademark of Pain Care Lab.

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Resources for Children

There are also resources for children who start XEMBIFY therapy. These materials include an educational book (*Our Immune System*, from the Immune Deficiency Foundation), and a therapy journal with crayons and stickers to help children be more involved and track their infusions.



DEDICATED SUPPORT THROUGH XEMBIFY CONNEXIONS

Starting a new treatment can be stressful for patients and caregivers. And long-term therapy can bring its own concerns. Xembify Connections is committed to providing you with strong support right from the start.

Financial support

Now with maximum copay support

- XEMBIFY now offers copay assistance up to \$10,000 per calendar year for eligible patients*
- Now with even more copay support, you may be eligible to pay as little as \$0 out of pocket
 - » Covers copayments, deductibles, and coinsurance
 - » Available whether the claim is billed under a pharmacy benefit or a medical benefit
 - » No monthly caps or infusion limits
 - » Your specialty pharmacy will enroll you with your provided consent



Patient assistance program

- You may be qualified to receive XEMBIFY at no cost, in the event that you lose insurance coverage



*Subject to terms and conditions.

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SUPPORT FROM A SINGLE, DEDICATED POINT OF CONTACT

You can contact Xembify Connexions and a representative can explain additional resources to you, including coverage, educational information, and more.

Coverage and resources partner

- Helps identify the best available benefits coverage for XEMBIFY
- Provides educational information and resources to address your healthcare needs

Ongoing support and education

- Answers questions about XEMBIFY, how it works, what to expect, and much more
- Provides information and support to help you manage your condition and make informed decisions about your treatment
- Connects you to organizations that support patients with PIDD and their caregivers

**A key to successful treatment is to have a
strong support team behind you right from the start.**

Call your dedicated Xembify Connexions team today:

**1-844-MYXEMBIFY (1-844-699-3624)
Monday through Friday 8 AM to 8 PM ET.**

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?

- **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
- **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

- **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.



GET THE MOST OUT OF XEMBIFY WITH PERSONALIZED SUPPORT



**Call 1-844-MYXEMBIFY (1-844-699-3624) for more information, support,
and financial needs Monday through Friday 8 AM to 8 PM ET.**

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