

START YOUR JOURNEY TOWARD MORE GOOD DAYS*

WITH XEMBIFY FOR PI

Count on XEMBIFY for the
power of pure protection¹⁻³



COUNT ON THE POWER OF
PURE PROTECTION

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

PI, primary immunodeficiency disease.

*In a clinical study; Zero serious bacterial infections (rate per subject-year: 0.049). Zero hospitalizations due to infections (rate per subject-year: 0.049). One patient reported sepsis due to an animal bite, an event deemed unrelated to treatment; this event was included in the calculations, giving an annual rate of 0.049 events per subject-year (N=49). Fewer than 3 days of work or school missed due to infections.²

GRIFOLS

Please see Important Safety Information for XEMBIFY on
pages 20-21 and full [Prescribing Information](#).

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IG, immune globulin; PI, primary immunodeficiency disease.

Please see **Important Safety Information for XEMBIFY** on pages 20-21 and full [Prescribing Information](#).



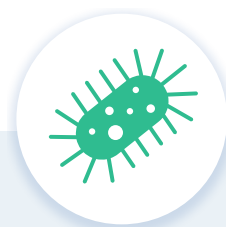
ABOUT PI

PEOPLE WITH PI HAVE AN IMMUNE SYSTEM THAT DOES NOT FIGHT OFF INFECTIONS WELL ENOUGH^{4,5}

There are more than 550 conditions of primary immunodeficiency, or PI.⁶ With primary immunodeficiency, part of your immune system, which protects you from infections and fights off diseases, is missing or doesn't function properly. As a result, your body can't protect you from germs as well as it should, so you are more likely to develop infections and get sick more often.^{4,5}



People with PI may experience frequent infections, such as sinus infections, ear infections, or pneumonia.^{4,7}



These infections may keep coming back and may last longer or be more severe than expected.^{4,7}

PI may be inherited, which means it is carried through the genes of your parents. If you have the disease, you may pass it along to your children, but you won't give it to anyone else.⁸

Having PI can be difficult, but you are certainly not alone. There are FDA-approved treatment options and lots of support available.

To explore patient support resources, visit:

<https://www.xembify.com/en/patients/xembify-connexions>

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PI SYMPTOMS AND DIAGNOSIS

The signs and symptoms of PI vary from person to person. If someone you know is experiencing any of the symptoms below, encourage them to talk to their doctor. Early detection of PI can help prevent long-term problems.⁴



CHRONIC RECURRING INFECTIONS

Sinus infections, bronchitis, and ear infections, which are more severe, longer lasting, and more difficult to cure than is typical^{4,7,9}



FREQUENTLY GETTING SICK WITH INFECTIONS

People with PI often get infections, such as the common cold, that a healthy immune system would be able to fight off.^{4,7,9}



NEED FOR ANTIBIOTICS

People who have PI are frequently prescribed antibiotics to treat or prevent infections. They often need longer treatment or stronger antibiotics than people who do not have PI.^{4,7,9}

If a person is experiencing recurrent and/or chronic infections, lab testing may be necessary to detect the presence of PI. The patient's medical history and physical exam will help determine the appropriate choice of lab tests. Blood samples and analysis of DNA (the material in your cells that carries genetic information) can be used to confirm a particular diagnosis.⁴

DNA, deoxyribonucleic acid; PI, primary immunodeficiency disease.

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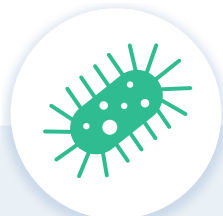
THE IMMUNE SYSTEM IN PEOPLE WITH PI

The immune system is an incredible network of cells, proteins, tissues, and organs that defends the body against a wide variety of germs every day. One important component of the immune system is antibodies.⁴

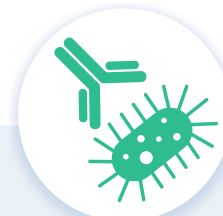
HOW DO ANTIBODIES WORK?



The body's immune system makes special proteins called antibodies.⁴



When the body detects a threat, such as a germ that can make you sick, it responds by making antibodies.⁴



Antibodies defend the body by attaching to the threat and signaling the body to destroy the germ.⁴

Usually, the immune system does a great job protecting the body from threats. But in people who have PI, the immune system doesn't work properly. In some cases, the immune system may not work at all.⁴



With a lower amount of antibodies, or antibodies that are not working properly, infections are more likely to occur.⁴

PI, primary immunodeficiency disease.

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ABOUT IG REPLACEMENT THERAPY

IG stands for immune globulin. It is made up of proteins taken from human plasma and contains purified antibodies that help your body fight infections. IG replacement therapy helps give your immune system these infection-fighting antibodies.¹⁰⁻¹²

IG THERAPY CAN BE GIVEN IN 2 WAYS⁴:



SCIG

Infused just below the skin
(subcutaneously)



IVIG

Infused through a vein,
typically in the arm
(intravenously)



Starting IG therapy soon after you are diagnosed with PI can help reduce your risk of permanent health issues.¹²

To access helpful resources, visit:

<https://www.xembify.com/en/patients/resources-and-information>

IVIG, intravenous immunoglobulin; PI, primary immunodeficiency disease;
SCIG, subcutaneous immunoglobulin.

Please see Important Safety Information for XEMBIFY on pages 20-21 and full [Prescribing Information](#).

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TALK TO YOUR DOCTOR ABOUT YOUR IG THERAPY OPTIONS

Whether you are new to IG or considering changing your IG treatment, you can make choices about your experience. Here are a few things you can discuss in an open and honest conversation with your doctor:

IF YOU ARE NEW TO IG

- Do you want to get your IG infusions at home or in a medical office or infusion center?
- Is it more important to you to have shorter infusion times or a longer time between infusions?

IF YOU ARE CURRENTLY TAKING IG

- Do you experience side effects, such as headache or nausea with your treatment?
- After your infusions, are you so tired you have to cancel activities that day or even the next day or two?



Not all IG therapies are the same¹³

It's important to talk to your doctor about what to expect before starting IG therapy.

IG, immune globulin.

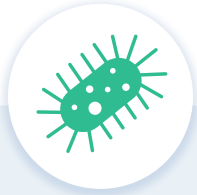
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COUNT ON XEMBIFY FOR INFECTION PROTECTION²

For people ages 2 years and older, whether they've received IG therapy before or not, XEMBIFY has been proven in clinical studies to be well tolerated throughout treatment.^{1,2,14}

IN A CLINICAL STUDY, PEOPLE WITH PI TAKING XEMBIFY HAD²:



0 serious bacterial infections^{2*†}



0 hospitalizations due to infection^{2†}



fewer than 3 days of work or school missed due to infections²



Get infection protection with a low rate of headaches²

In a clinical study, 1 patient experienced headache and the rate of headaches was 1 in every 1000 infusions.

IG, immune globulin; PI, primary immunodeficiency disease.

*One patient reported sepsis due to an animal bite, an event deemed unrelated to the treatment.²

†Rate per subject-year: 0.049.²

XEMBIFY[®] (immune globulin subcutaneous human-klhw) is a 20% immune globulin used in the treatment of primary humoral immunodeficiency disease (PIHD) in patients 2 years of age and older. XEMBIFY is for subcutaneous administration only.¹

Please see Important Safety Information for XEMBIFY on pages 20-21 and full [Prescribing Information](#).

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

MOST COMMON SIDE EFFECTS WITH XEMBIFY¹

The most common side effects in a clinical study of patients with PI who received XEMBIFY were¹:

- Infusion-site reactions such as redness, pain, puffiness, swelling, bruising, nodule or scab formation, itching, and firmness
- Cough and diarrhea

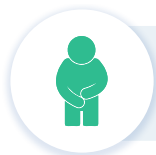
Tell your healthcare provider if you have or ever had¹:

- A serious reaction to other medicines that contain immune globulin
- An immunoglobulin A (IgA) deficiency
- A history of heart or blood vessel disease
- A risk factor for blood clots
- Inability to move over the course of a few hours

XEMBIFY WAS PROVEN TOLERABLE IN CLINICAL STUDIES^{1,2}:



0 serious infusion reactions^{1,2}



0 reports of nausea



0 reports of fatigue²



fewer than 1 headache per 1000 infusions²

PI, primary immunodeficiency disease.

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GET CONSISTENT PROTECTION BETWEEN DOSES WITH XEMBIFY²

XEMBIFY raises your IgG levels quickly and keeps them there to keep you protected between doses.^{2,15}

IN A CLINICAL TRIAL WITH XEMBIFY²:



Most people had IgG levels above the commonly accepted level to fight infection in an average of 3 days.



People's IgG levels *stayed* above the commonly accepted level even between doses, delivering uninterrupted infection protection.

What does this mean?

When IgG levels are maintained, you can get continuous infection protection without feeling sick because your treatment has started wearing off.¹⁵

COUNT ON  THE POWER OF
PURE PROTECTION

with XEMBIFY, an IG therapy that contains $\geq 98\%$ IgG and is designed to replace what your body doesn't make itself¹⁻³

IG, immune globulin; IgG, immunoglobulin G.

Please see Important Safety Information for XEMBIFY on pages 20-21 and full [Prescribing Information](#).

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GET INFECTION PROTECTION FROM THE START WITH XEMBIFY^{2,14}

Whether you are new to IG or switching from another IG product, you and your doctor can decide together how often to administer XEMBIFY (from daily up to every 2 weeks) so it fits into your life. You can stay protected and minimize unwanted side effects with the flexible dosing of XEMBIFY.^{1,2,14}

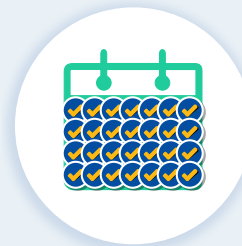
XEMBIFY IS PROVEN TO BE WELL TOLERATED ACROSS MULTIPLE DOSING SCHEDULES^{1,14}



Every 2 Weeks



Weekly



Daily

- XEMBIFY is the **first and only** 20% SCIG therapy for PI that does not require an IVIG loading dose to start¹
- XEMBIFY is concentrated to 20% IG during manufacturing to reduce the volume needed for each infusion³
- In clinical studies, XEMBIFY was well tolerated across multiple dosing schedules^{1,14}

Watch the XEMBIFY self-administration video online

To learn more about self-infusion at home or wherever is most convenient for you, or visit:

www.xembify.com/en/patients/infusing-xembify

IG, immune globulin; IVIG, intravenous immunoglobulin; PI, primary immunodeficiency disease; SCIG, subcutaneous immunoglobulin.

Please see Important Safety Information for XEMBIFY on pages 20-21 and full [Prescribing Information](#).

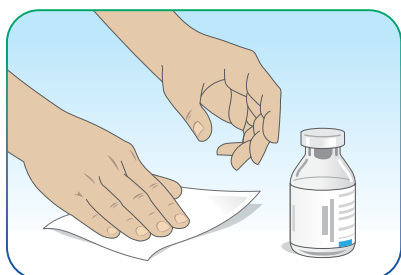
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INFUSING XEMBIFY

BEFORE THE INFUSION

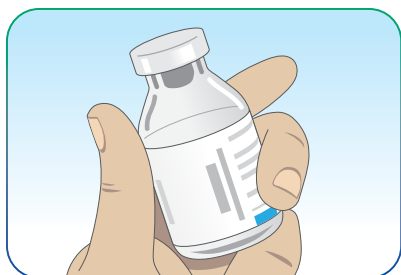
If the vial(s) of XEMBIFY is refrigerated, remove from the refrigerator prior to your infusion and allow the vial(s) to reach room temperature. This may take 60 minutes or longer. **Do not** apply heat to the vial(s) or place in the microwave. Instead, let the vial(s) warm to room temperature naturally.¹

FOLLOW THESE STEP-BY-STEP INSTRUCTIONS ON HOW TO INFUSE



STEP 1

Disinfect surface to be used for your infusion with an alcohol wipe. Allow the vial(s) of XEMBIFY to reach room temperature. Set up all the supplies you will need. Wash and dry your hands thoroughly.¹



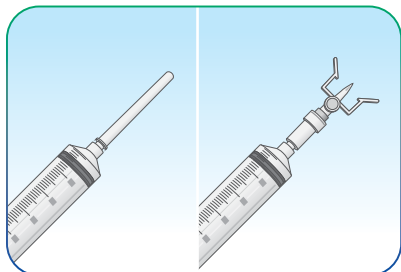
STEP 2

Check the vial(s) of XEMBIFY. Confirm the name and expiration date. If the product is past the expiration date, if the liquid is cloudy or has particles, or if the vial shows any sign of tampering, do not use that vial. Tell your healthcare provider immediately.¹



STEP 3

Remove the tamper-resistant seal and protective cap from the vial of XEMBIFY. Clean the rubber stopper with an alcohol wipe and allow to air dry.¹



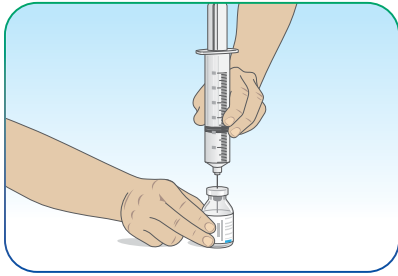
STEP 4

Draw XEMBIFY into the syringe using either a needle or a transfer device. If you are using a needle, refer to Step 5. If using a transfer device, refer to Step 6.^{1,16}

Please see Important Safety Information for XEMBIFY on pages 20-21 and full [Prescribing Information](#).

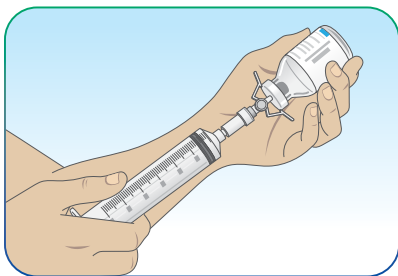
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INFUSING XEMBIFY (cont.)



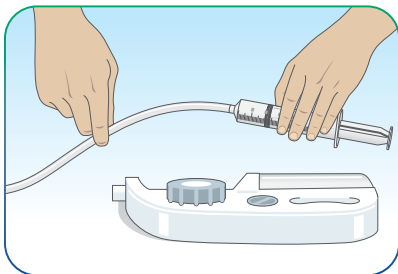
STEP 5

Attach the needle to the syringe tip and remove the cap. Pull the syringe plunger back to the level of XEMBIFY you want to withdraw. Place the vial on a flat surface, insert the needle, and inject air. Turn the vial and syringe upside down. Make sure the needle is placed below the fluid level and withdraw XEMBIFY. If using a needle in Step 5, skip to Step 7.¹



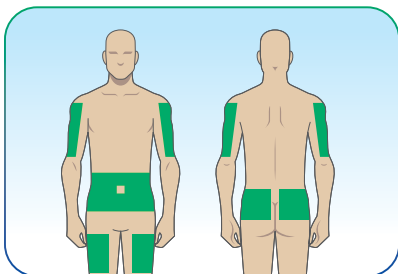
STEP 6

Uncap the transfer device and attach it to the syringe. Place the vial on a flat surface and insert the device into the top of the vial. Turn the vial and syringe upside down and withdraw the desired amount of XEMBIFY. Then, remove the syringe and transfer device.¹⁶



STEP 7

Follow the pump manufacturer's instructions to attach the infusion tubing and needle set to the syringe. Be sure to prime the administration tubing by filling it with XEMBIFY. Make sure the needle remains dry while priming.^{1,17}



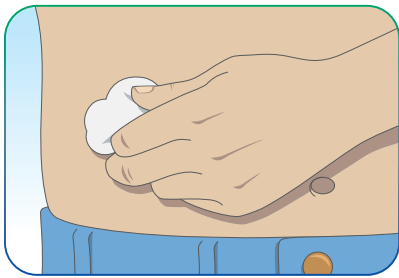
STEP 8

XEMBIFY may be infused in the abdomen, thigh, upper arm, sides, back, or hip. Select one or more infusion sites as directed by your healthcare provider. Be sure to choose sites that are different from your last infusion.^{1,16}

Please see Important Safety Information for XEMBIFY on pages 20-21 and full [Prescribing Information](#).

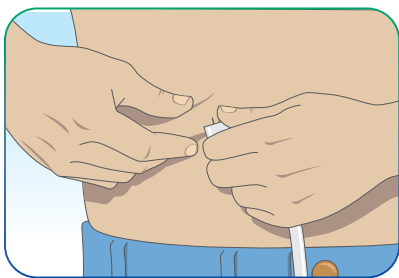
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INFUSING XEMBIFY (cont.)



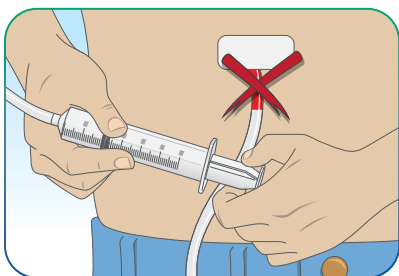
STEP 9

Prepare the infusion site(s) by cleaning with an alcohol wipe. The sites should be clean, dry, at least 2 inches apart, and 2 inches away from the belly button. Do not use more than 6 infusion sites at the same time.^{1,17}



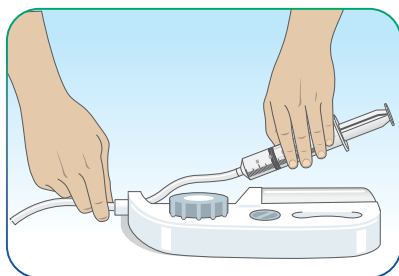
STEP 10

Grasp the skin between 2 fingers and insert the needle into the subcutaneous tissue (tissue underneath the skin).¹



STEP 11

Make sure a blood vessel has not been entered. If you see blood when pulling back on the plunger, remove and discard the needle and tubing. Repeat Steps 8 to 10 using a new needle, administration tubing, and a new infusion site. Secure needle with an adhesive dressing. Repeat for the other sites as needed.¹



STEP 12

Follow the pump manufacturer's instructions to load the syringe and start the infusion. The 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.^{1,17}

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AFTER THE INFUSION¹

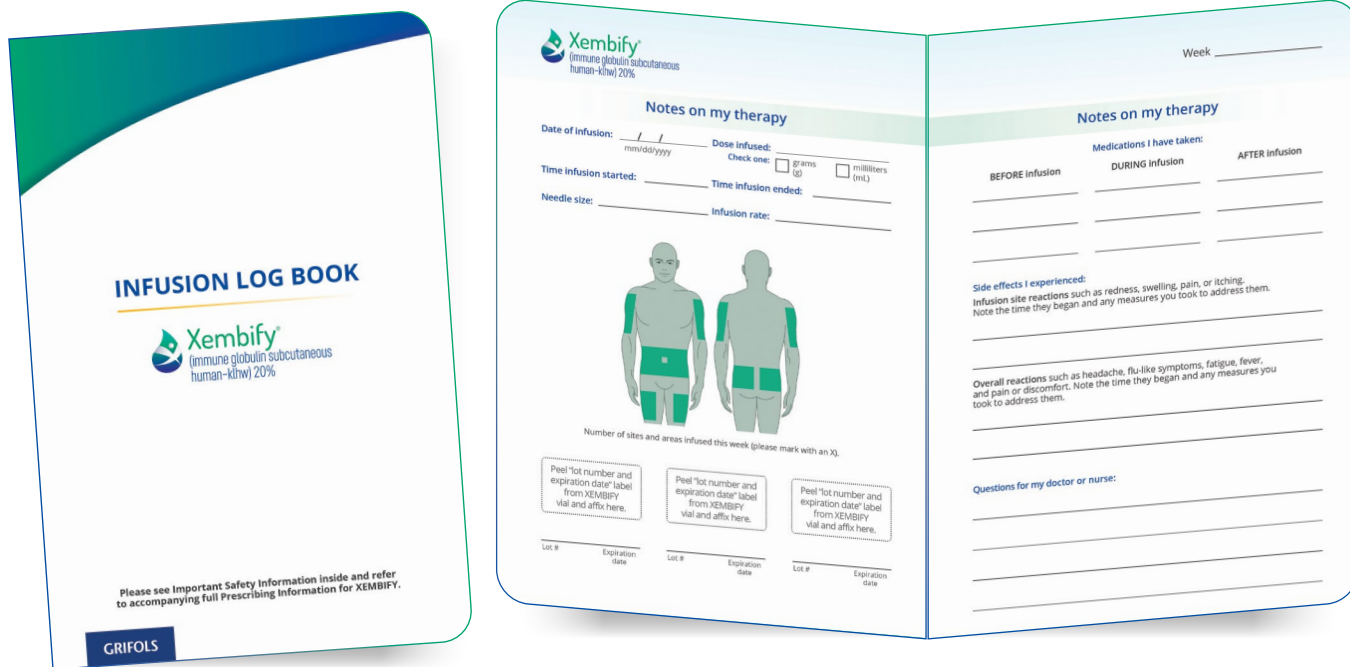
- ✓ Wash your hands again
- ✓ Follow the manufacturer's instructions to turn off the pump
- ✓ Undo and discard any dressing or tape
- ✓ Gently remove inserted needle(s)
- ✓ Discard the used needles and tubing in a sharps container
- ✓ Discard any unused solution in an appropriate waste container
- ✓ Store your supplies in a safe place
- ✓ Follow the manufacturer's instructions to care for the infusion pump
- ✓ Record the infusion in the Infusion Log Book in your XEMBIFY Starter Kit



Please see **Important Safety Information** for XEMBIFY on pages 20-21 and full [Prescribing Information](#).

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TRACK YOUR TREATMENT WITH THE INFUSION LOG BOOK



Your XEMBIFY Starter Kit will include an Infusion Log Book. Record each infusion in your Infusion Log Book to help you keep track of your infusions and how you are feeling.

Once you have completed the Infusion Log Book included in your Starter Kit, you can download a new one from the XEMBIFY website or:

Call Xembify Connexions at **1-844-MYXEMBIFY (1-844-699-3624)**
Monday through Friday 8 AM to 8 PM ET to order a new one



To order online, visit:

<https://www.xembify.com/en/patients/xembify-connexions>



Record each infusion in your log book and remember to share it with your healthcare provider at your next visit.

Please see Important Safety Information for XEMBIFY on pages 20-21 and full [Prescribing Information](#).



DEDICATED SUPPORT THROUGHOUT TREATMENT

Xembify Connexions™ PROVIDES FINANCIAL SUPPORT FOR ELIGIBLE PATIENTS, INCLUDING:

- Eligible patients may have as little as \$0 copay*
- Up to \$10,000 copay assistance per calendar year to help with deductibles, copayments, and coinsurance medication cost for XEMBIFY
- Patient Assistance Program that provides no-cost medication for eligible patients without insurance

Xembify Connexions OFFERS ONGOING SUPPORT FROM A SINGLE, DEDICATED POINT OF CONTACT



Educational resources about PI and XEMBIFY



Information about benefits coverage for XEMBIFY



Knowledge and support to help you manage PI and make informed decisions

Call Xembify Connexions at 1-844-MYXEMBIFY (1-844-699-3624)
Monday through Friday 8 AM to 8 PM ET



Xembify
connexions™

PI, primary immunodeficiency disease.

*Subject to terms and conditions.

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FIND SUPPORT FROM TRUSTED ORGANIZATIONS

You are not alone in your journey with PI. These organizations offer education, advocacy, and support:

- The Immune Deficiency Foundation (IDF) - www.primaryimmune.org
 - Patient and physician resource for the research and education of primary immunodeficiency disease
- The Jeffrey Modell Foundation - www.info4pi.org
 - Global resource center for PI that provides patient and physician materials, including a patient message board
- The International Patient Organisation for Primary Immunodeficiencies (IPOPI) - www.ipopi.org
 - An international organization dedicated to advancing PI clinical care through medical education and global collaboration
- The National Institute of Allergy and Infectious Diseases (NIAID) - www.niaid.nih.gov
 - Part of the National Institutes of Health, the NIAID leads research to understand, treat, and prevent infectious, immunologic, and allergic diseases

These websites are provided as a resource only and do not constitute an endorsement by Grifols of any particular content. Grifols does not review or control the content of non-Grifols websites.

PI, primary immunodeficiency disease.



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IMPORTANT SAFETY INFORMATION

What is XEMBIFY®?

XEMBIFY® (immune globulin subcutaneous human-klhw) is a 20% immune globulin used in the treatment of primary humoral immunodeficiency disease (PID) 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.

Please see full [Prescribing Information](#) for XEMBIFY.



IMPORTANT SAFETY INFORMATION (cont.)

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 the 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.

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IgG, immunoglobulin G; IVIG, intravenous immunoglobulin.

*In patients 2 years of age and older.¹

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.¹

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.¹

GRIFOLS

Please see Important Safety Information for XEMBIFY on pages 20-21 and full [Prescribing Information](#).

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