Xembify® connexions

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

XEMBIFY CONNEXIONS PATIENT CONSENT FORM

Thank you for your interest in the Xembify Connexions Program for ongoing financial and dedicated medical support. In order to enroll, please complete and return this form by mail or fax. We are here to support you every step of the way.

1. COMPLETE THE FORM BELOW

YOUR INFORMATION:

Name: _____ Date of birth: _____
(First name, Middle initial, Last name) (mm/dd/yyyy)

Parent or guardian name (if patient is under age 18 years): _____

Address: _____ City: _____ State: _____ ZIP: _____

Phone: _____ Email: _____

I am a: ☐ Patient ☐ Caregiver ☐ Other

PATIENT AUTHORIZATION:

☐ By checking this box, I authorize my healthcare providers, pharmacies, health plans, or payers ("my healthcare organizations") to share personal and health information about me related to my Grifols therapies ("my information") with Grifols, its affiliates, agents, and contractors. I understand that once my information is shared with Grifols, my information may not be protected by federal health privacy laws. Grifols agrees to protect my information and to use and share it only for the reasons listed below. I understand that my pharmacy may receive compensation in connection with sharing my information with Grifols as allowed under this Authorization. I authorize Grifols to: (1) contact me, my caregiver, or my healthcare organizations about my disease or treatment; (2) confirm my health plan eligibility and benefits, identify other payers for my therapy, or determine my eligibility for assistance programs; (3) analyze data to improve services related to my disease; (4) contact me by e-mail, mail, or telephone (including text and voicemail); and (5) disclose my information for safety reasons or as required by law. This Authorization will expire 5 years from the date signed below unless a shorter period is required by the law of my state of residence. I may discuss the scope of my authorization or cancel at any time by calling 1-844-MYXEMBIFY and/or by writing a letter to Xembify Connexions to PO Box 31137, Bethesda, MD 20824.

XEMBIFY CONNEXIONS PATIENT EDUCATION PROGRAM ENROLLMENT:

☐ By checking this box, I agree to enroll in an **optional** disease-related support program. I agree to give Grifols permission to use my personal information to receive product, disease-state, and other helpful information from Grifols, and service providers and third parties acting on its behalf. You may revoke your permission at any time. To learn how Grifols will use and protect your personal information, please review our privacy policy at USprivacypolicy.grifols.com.

Patient First and Last Name (print): _____

PATIENT SIGNATURE: _____ Date: _____

Patient Caregiver (name and relationship): _____

***CAREGIVER SIGNATURE:** _____ Date: _____

**Parent or guardian must sign if patient is below 18 years of age.*

2. RETURN COMPLETED FORM

Mail
Xembify Connexions
PO Box 31137
Bethesda, MD 20824

Fax
1-877-375-0758

QUESTIONS & ADDITIONAL INFORMATION

Questions
Call 1-844-MYXEMBIFY (1-844-699-3624) or visit www.xembify.com to access Xembify Connexions tools and resources

Forms
If needed, download additional forms at www.xembify.com

You may make changes to communication preferences or cancel your enrollment in this program at any time by calling 1-844-MYXEMBIFY (1-844-699-3624).

Please see Important Safety Information on the reverse side and see accompanying full Prescribing Information for XEMBIFY® (immune globulin subcutaneous human-klhw).

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(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 (Sub-Q) 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 lay 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 meninges which 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, your doctor 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, your doctor 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, your doctor 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.

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