Xembify connexions™

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

PRESCRIPTION REFERRAL FORM

Please fax completed form to 1-877-375-0758

PATIENT INFORMATION: *Required to process*

Name:

Date of birth (dd/mm/yyyy): / / ☐ Male ☐ Female

Address:

City: State: ZIP:

Phone: Email (optional):

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

Diagnosis code:

Current therapy (please check below, if applicable):

☐ IVIG ☐ Other SCIG

☐ New patient

PATIENT INSURANCE INFORMATION: *Required to process — Please provide a copy of the front and back of the insurance cards*

Primary medical insurance: Insurance phone: Policy ID: Group ID:

Policy holder name: Relationship to patient: Date of birth (dd/mm/yyyy): / /

Primary prescription drug insurance: Pharmacy plan phone:

Policy ID: Group ID: Rx BIN: Rx PCN:

Secondary medical insurance: Insurance phone: Policy ID: Group ID:

Policy holder name: Relationship to patient: Date of birth (dd/mm/yyyy): / /

COORDINATION OF CARE:

Preferred site of care: ☐ Outpatient infusion center ☐ Physician office ☐ Home ☐ Other:

Preferred specialty pharmacy Facility name: Contact name: Title: Phone:

PRESCRIBER INFORMATION: *Required to process*

Physician name (print): Office contact:

City: State: ZIP: Phone: Fax:

Facility or prescriber tax ID#: NPI#: Email (optional):

PRESCRIBING INFORMATION (PIDD):

Sub-Q administration (PIDD only) Patient Height: (ft/in) Patient Weight: (lb) (kg)

mg/kg x 1.37 sub-Q every: (frequency)

Needle length (mm) – *check one (optional)*: ☐ 4 ☐ 6 ☐ 9 ☐ 12 ☐ 14 # Of sites *(optional)*: Refills: Premedication orders?: ☐ Yes ☐ No

Other medications (specify): Drug allergies:

☐ Provide any medical/ancillary supplies as necessary to safely administer prescribed medication

☐ Provide pump and related infusion supplies

☐ Nursing services:

☐ Anaphylaxis kit:

☐ Other order(s):

☐ Tubing

I verify that the patient and prescriber information contained in this enrollment form is complete and accurate to the best of my knowledge and that I have prescribed XEMBIFY® (immune globulin subcutaneous human-klhw) 20% based on my professional judgment and medical necessity. I also attest that I have obtained the patient's affirmative authorization to release the above information and such other personal information as may be necessary to Xembify Connexions and/or their agents. I authorize Grifols and its affiliated companies, agents and representatives, and contracted third parties to forward this prescription electronically, by facsimile, or by mail to the dispensing pharmacy selected above (if applicable). If patient is younger than 18 years I attest that I have obtained permission from the patient's legal guardian.

PRESCRIBER SIGNATURE: *Required to process* Date:

☐ **DISPENSE AS WRITTEN:** Exact terminology may be based on state regulations. Please provide state-specific prescription language here.

If you have questions, please call Xembify Connexions toll free at 1-844-MYXEMBIFY (1-844-699-3624), Monday to Friday from 8 AM to 8 PM ET.

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

Please see Important Safety Information on the next page and refer to accompanying full Prescribing Information for XEMBIFY.

GRIFOLS

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

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, 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

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.

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.

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.

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.

GRIFOLS