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Grifols Australia is pleased to announce XEMBIFY® (normal immunoglobulin (Human) 20% solution for subcutaneous injection) is now available for prescribing under the National Blood Supply arrangements and will be available for supply in January 2024.

The approved access conditions for subcutaneous immunoglobulin (SCIg) under the National Blood Supply arrangements are outlined on the National Blood Authority website at:

https://www.blood.gov.au/SCIg

INDICATION

XEMBIFY®, administered subcutaneously, is registered for use as:

Replacement therapy in adult and paediatric patients for:

- Primary immunodeficiency diseases (PID)
- Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment

PACK SIZES AND ADMINISTRATION

XEMBIFY® is available in the following vial sizes:

- 1 g in 5 mL
- 2 g in 10 mL
- 4 g in 20 mL
- 10 g in 50 mL

The dose may need to be individualised for each patient dependent on the pharmacokinetic and clinical response. For more details on dosage and administration, please review the XEMBIFY® Product Information:

https://www.gatewayhcpportal.com.au/documents/3523457/3528032/Xembify+Product+Information.pdf/9d37a8f4-e443-920b-4d07-6ce78962f458?t=1686299729483

PATIENT SUPPORT PROGRAM

Grifols XEMBIFY® Connex Patient Support Program (PSP) will be available for Australian patients prescribed XEMBIFY®. The PSP will provide patients with access to qualified nurses for in-home training on the self-administration of XEMBIFY® to supplement the initial training provided at their healthcare facility. For additional information about the PSP, please contact Grifols Australia Medical Information on 1800 339 479 or email australia_medinfo@grifols.com .

Grifols Australia Pty Ltd ABN 35 050 104 875

ADDITIONAL INFORMATION

For additional information about Xembify, please contact Grifols Australia Medical Information on 1800 339 479 or email australia_medinfo@grifols.com . Adverse events related to XEMBIFY® (normal immunoglobulin (Human) 20% solution for subcutaneous injection) should be reported by healthcare professionals to Grifols Australia Medical Information on 1800 339 479 or by email to australia_medinfo@grifols.com Alternatively, this information can be reported to the TGA.

Please review the Product Information before prescribing.

PBS Information: This Product is not listed on the PBS. Please refer to the National Blood Authority for details.

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PLEASE REVIEW PRODUCT INFORMATION BEFORE PRESCRIBING. PRODUCT INFORMATION IS AVAILABLE ON REQUEST FROM GRIFOLS AUSTRALIA PTY LTD BY EMAIL: AUSTRALIA_MEDINFO@GRIFOLS.COM OR ONLINE FROM https://www.gatewayhcpportal.com.au/documents/3523457/3528032/Xembify+Product+Information.pdf/9d37a8f4-e443-920b-4d07-6ce78962f458?t=1686299729483

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

MINIMUM PRODUCT INFORMATION. XEMBIFY® Normal Immunoglobulin (Human) 20% solution for subcutaneous injection. **INDICATIONS:** Replacement therapy in adult and paediatric patients for primary immunodeficiency diseases (PID) and symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment. **CONTRAINDICATIONS:** Must not be given intravascularly or intramuscularly. Patients who have had an anaphylactic or severe systemic reaction to the administration of normal immunoglobulin (IG) or any of its excipients. IgA deficient patients with antibodies against IgA and history of hypersensitivity to IG treatment. **PRECAUTIONS:** Shock may occur if accidentally administered into a blood vessel. The recommended infusion rate given in the Product Information must be closely followed. Monitor closely and observe carefully throughout the infusion period. Certain adverse reactions may occur more frequently in patients who receive IG for the first time or, in rare cases, when the IG product is switched or if a long interval since previous infusion. True allergic reactions are rare but can particularly occur in patients with anti-IgA antibodies. Arterial and venous thromboembolic events including myocardial infarction, stroke, deep venous thrombosis and pulmonary embolism have been associated with the use of IG. Severe renal adverse reactions have been reported in patients receiving IG treatment. Aseptic meningitis syndrome has been reported to occur in association with subcutaneous IG treatment; the symptoms usually begin within several hours to 2 days. A positive direct antiglobulin reaction and, rarely, haemolysis may occur; acute

haemolysis consistent with intravascular haemolysis has been reported. Transfusion-related acute lung injury (TRALI) may occur in patients following treatment with IG products. There are no known specific considerations with regard to patients with hepatic impairment. Use caution when administering Xembify® to patients aged ≥65 who are at increased risk for thrombosis. Paediatric patients aged <2 years were not included in studies so there is lack of data. After injection of IG, the transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing. **ADVERSE EFFECTS:** Chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain may occur occasionally. Rarely IG may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration. Local reactions at infusion sites: swelling, soreness, redness, induration, local heat, itching, bruising and rash, may frequently occur. **DOSAGE AND ADMINISTRATION:** Dosage: The dose may need to be individualised for each patient dependent on the pharmacokinetic and clinical response. The following dosage regimens are given as a guideline: the dose regimen should achieve a trough level of IgG (measured before the next infusion) of ≥5–6 g/l and aim to be within the reference interval of serum IgG for age. After steady state IgG levels have been attained, administer maintenance doses at repeated intervals (~1/week) to reach a cumulative monthly dose of 0.4–0.8 g/kg. Trough levels should be measured and assessed in conjunction with incidence of infection. Clinical response should be the primary consideration in dose adjustment. Method of administration: For subcutaneous use only; may be injected into sites such as abdomen, thigh, upper arm and lateral hip. Infusion pumps appropriate for subcutaneous administration of IG can be used. The recommended initial infusion rate depends on the individual needs of the patient and should not exceed an administration speed of 25 ml/h/site. If well tolerated for two infusions, infusion speed can gradually be increased to 35 ml/h/site. In infants and children, infusion sites may be changed every 5–15 ml. In adults, doses >30 ml may be divided according to patient preference. There is no limit to the number of infusion sites. Infusion sites should be ≥5 cm apart. For single use in one patient only. Discard any residue.

SPONSOR: Grifols Australia Pty Ltd, Unit 5/80 Fairbank Road, Clayton South, VIC 3169 Australia**. Medical Information**: 1800 339 479. **Email:** australia_info@grifols.com. Date of Preparation: July 2022 based on Product Information approved 30 June 2022.