Generic Name:
20% subcutaneous immunoglobulin
Trade Name:
Xembify
Company:
Grifol
Notes:

FDA has approved Grifol's 20% immunoglobulin for S.C. injection to treat primary humoral immunodeficiency in patients ages 2 years and older. It can also be used to treat rare neurological conditions, such as chronic inflammatory demyelinating polyneuropathy.

The product has a boxed warning on the risk of thrombosis. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of 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, clinicians should administer at the minimum dose and infusion rate practicable, and ensure adequate hydration before administration. Clinicians should also monitor for signs and symptoms of thrombosis, and assess blood viscosity in patients at risk for hyperviscosity.

Common adverse reactions are infusion site erythema, pain, swelling, bruising, nodule, pruritus, induration, scab, and edema; as well as systemic reactions such as cough and diarrhea.

Grifols plans to launch the product in the United States in the last quarter of 2019.

Medication Monitor Categories:
New Drug Approvals