CUTAQUIG (Immune Globulin Subcutaneous (Human) - hipp) is a 16.5% immune globulin solution for subcutaneous (SC) immunoglobulin therapeutic use. It is a single-use vial containing 50 mg/mL of immunoglobulin. The volume of each SC dose is provided in the full prescribing information. It is intended for use in patients who do not respond adequately to intravenous immunoglobulin therapy. The packaging includes information on administration, storage, and disposal of the product. The product contains ≤ 0.6 mg of IgA/mL.

**DOSAGE FORMS AND STRENGTHS**

CUTAQUIG is available as 50 mg/mL (10 mL vial), 75 mg/mL (15 mL vial), and 100 mg/mL (20 mL vial) in single-use vials. Each vial contains 50 mg of immunoglobulin.

**FULL PRESCRIBING INFORMATION**

See full prescribing information for complete boxed warning.

**WARNINGS AND PRECAUTIONS**

1. **Thrombosis**
   - Thrombosis may occur in the absence of known risk factors. It is recommended to follow the National Comprehensive Cancer Network (NCCN) guidelines for thromboprophylaxis.
   - Ensure that patients have received IGSC at regular intervals for at least 3 months before switching from IGIV.

2. **Immune system disorders**
   - Non-cardiogenic pulmonary edema may occur in patients administered human immune globulin therapy due to enhanced RBC sequestration, and acute hemolysis, consistent with TRALI.
   - TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal or decreased cardiac output, and a normal white blood cell count. Underlying immune system disorders and cardiovascular risk factors may increase the risk of TRALI.
   - Do not use in patients with a history of TRALI or a history of non-O blood group.
   - Ensure that the total weekly dose is maintained, any dosing interval from daily up to weekly can be used.
   - Do not use in patients with a history of venous or arterial thrombosis, use of estrogens, indwelling catheters, or chronic hypotension.
   - Ensure that patients have received Immune Globulin Intravenous (Human) (IGIV) treatment at regular intervals for at least 3 months before switching from IGIV.

3. **Immune globulin products**
   - There have been reports of TRALI following administration of immune globulin products. TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal or decreased cardiac output, and a normal white blood cell count. Underlying immune system disorders and cardiovascular risk factors may increase the risk of TRALI.
   - Do not use in patients with a history of TRALI or a history of non-O blood group.
   - Ensure that the total weekly dose is maintained, any dosing interval from daily up to weekly can be used.
   - Do not use in patients with a history of venous or arterial thrombosis, use of estrogens, indwelling catheters, or chronic hypotension.
   - Ensure that patients have received Immune Globulin Intravenous (Human) (IGIV) treatment at regular intervals for at least 3 months before switching from IGIV.

4. **Preparing the infusion pump and tubing**
   - Follow the manufacturer’s instructions for preparing the infusion pump.
   - Ensure that the total weekly dose is maintained, any dosing interval from daily up to weekly can be used.
   - Do not use in patients with a history of venous or arterial thrombosis, use of estrogens, indwelling catheters, or chronic hypotension.
   - Ensure that patients have received Immune Globulin Intravenous (Human) (IGIV) treatment at regular intervals for at least 3 months before switching from IGIV.

5. **Dressing selection**
   - Select a sterile dressing that is appropriate for the patient’s skin type and condition.
   - Ensure that the total weekly dose is maintained, any dosing interval from daily up to weekly can be used.
   - Do not use in patients with a history of venous or arterial thrombosis, use of estrogens, indwelling catheters, or chronic hypotension.
   - Ensure that patients have received Immune Globulin Intravenous (Human) (IGIV) treatment at regular intervals for at least 3 months before switching from IGIV.

6. **Adverse reactions**
   - The most common adverse reactions (ATC code: C12A) include: injection site reactions, flushing, headache, pruritus, and urticaria.
   - Do not use in patients with a history of venous or arterial thrombosis, use of estrogens, indwelling catheters, or chronic hypotension.
   - Ensure that patients have received Immune Globulin Intravenous (Human) (IGIV) treatment at regular intervals for at least 3 months before switching from IGIV.
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