CONTRAINDICATIONS

- Patients who are allergic to human immunoglobulin products, including CUTAQUIG
- Patients who may develop an allergic reaction as a result of previous systemic administrations of human immunoglobulin products
- Patients who develop an allergic reaction during the infusion
- Patients with agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe humoral immunodeficiency
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients who have been treated with human immunoglobulin products containing FcγRIIIa polymorphisms
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobulin products
- Patients with a history of anaphylactic reaction to human immunoglobu...
Non-Enveloped Viruses
Grams Protein
PPV
Press a small piece of gauze on the needle site and apply
1.5 (0.4)
Figure 7
Pinch the skin between your thumb and forefinger around
Remove the protective cap.
≥
Start the infusion. Follow infusion pump manufacturer’s

A pharmacokinetic (PK) sub-study was conducted in 18 adult subjects who were enrolled in the
material from not less than 1000 donors, has an IgG subclass distribution similar to that of native
subclasses closely proportional to that in native human plasma. The mechanism of action in primary
12.1
and chromatography. The manufacturing process includes treatment with an organic S/D mixture
The product is manufactured by the cold ethanol fractionation process followed by ultrafiltration
than 94% monomers and dimers, and not more than 3% fragments. On average, the product contains
CUTAQUIG (Immune Globulin Subcutaneous (Human) - hipp), is a solvent/detergent (S/D)-treated,

Risk Summary
8.1
8

Home treatment/Self administration
of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent
Inform patients to be tested periodically to make sure they have the appropriate levels of IgG in their
Advise the patients to read the FDA-approved patient labeling (Patient Information and Instructions

What are the possible or reasonably likely side effects of CUTAQUIG?

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Number of days</th>
<th>Annual rate of other infections per</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>treatment days per patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What should I tell my healthcare provider before using CUTAQUIG?

- Have you ever had a heart attack, a stroke or other blood vessel problem?
- Recent surgery or injury
- A heart valve problem
- Allergic reactions ever had to any ingredients in CUTAQUIG
- You are pregnant or plan to become pregnant or you are breastfeeding or planning to breastfeed

How should I use CUTAQUIG?

- Read the Product Information and Instructions for Use before you start using this medicine and
- Talk to your healthcare provider about how you can use glucose testing systems while using
- This Product Information and Instructions for Use is not a complete guide. You should read the
- Follow the instructions on the manufacturer’s label and follow the directions of your healthcare
- Inform your healthcare provider if you develop symptoms of infections or other medical problems
- Inform your healthcare provider if you develop symptoms of infections or other medical problems
- Inform your healthcare provider if you develop symptoms of infections or other medical problems
- Inform your healthcare provider if you develop symptoms of infections or other medical problems

How do I store and handle CUTAQUIG?

- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.

How do I store and handle CUTAQUIG?

- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.
- Keep the vial in the outer carton to protect it from light.
- Components used in the packaging of CUTAQUIG are not made with natural rubber latex.