WARNINGS AND PRECAUTIONS

1. Do not use with patients who have a known allergy to Gammaplex or components thereof.

2. Do not use with patients who have a known allergy to human immunoglobulin.

3. Do not use with patients who have a history of immediate or anaphylactic-type reactions to human gamma globulin products.

4. Do not use with patients who have a history of immediate or anaphylactic-type reactions to human gamma globulin products.

5. Do not use with patients who have a history of immediate or anaphylactic-type reactions to human gamma globulin products.

DOSAGE AND ADMINISTRATION

1. Use in the recommended dosage and frequency as described in the prescribing information.

2. Use in the recommended dosage and frequency as described in the prescribing information.

3. Use in the recommended dosage and frequency as described in the prescribing information.

4. Use in the recommended dosage and frequency as described in the prescribing information.

ADVERSE REACTIONS

1. The most common adverse reactions are headache, dizziness, and nausea.

2. The most common adverse reactions are headache, dizziness, and nausea.

3. The most common adverse reactions are headache, dizziness, and nausea.

4. The most common adverse reactions are headache, dizziness, and nausea.

5. The most common adverse reactions are headache, dizziness, and nausea.

USE IN SPECIFIC POPULATIONS

1. Use in patients with known antibodies to IgA may have a greater risk of developing anaphylactic reactions.

2. Use in patients with known antibodies to IgA may have a greater risk of developing anaphylactic reactions.

3. Use in patients with known antibodies to IgA may have a greater risk of developing anaphylactic reactions.

4. Use in patients with known antibodies to IgA may have a greater risk of developing anaphylactic reactions.

5. Use in patients with known antibodies to IgA may have a greater risk of developing anaphylactic reactions.

CONTRAINDICATIONS

1. Use in patients with immediate or anaphylactic-type reactions to human gamma globulin products.

2. Use in patients with immediate or anaphylactic-type reactions to human gamma globulin products.

3. Use in patients with immediate or anaphylactic-type reactions to human gamma globulin products.

4. Use in patients with immediate or anaphylactic-type reactions to human gamma globulin products.

5. Use in patients with immediate or anaphylactic-type reactions to human gamma globulin products.

NOTES

1. Note that the information provided is intended for healthcare professionals and is not designed for general public use.

2. Note that the information provided is intended for healthcare professionals and is not designed for general public use.

3. Note that the information provided is intended for healthcare professionals and is not designed for general public use.

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5. Note that the information provided is intended for healthcare professionals and is not designed for general public use.

REFERENCES

1. References are available upon request and may be obtained from the manufacturer.

2. References are available upon request and may be obtained from the manufacturer.

3. References are available upon request and may be obtained from the manufacturer.

4. References are available upon request and may be obtained from the manufacturer.

5. References are available upon request and may be obtained from the manufacturer.
There are three processing steps specifically designed to remove or inactivate viruses:

1. **Plasma Fractionation**: This step involves the separation of plasma from blood. Plasma is then treated with various agents to inactivate viruses. For example, plasma can be treated with high pH, detergent, or solvent-detergent steps to eliminate a wide range of viruses.

2. **Filtration**: Viruses can be further removed by filtration through a membrane with a pore size of 100 nanometers or less. This filtration step is efficient in removing viruses and other particulate matter.

3. **Heat Treatment**: This step involves heating the plasma to temperatures that are lethal to viruses. For instance, treating plasma to 80°C for 30 minutes can inactivate most enveloped viruses.

**DRUG INTERACTIONS**

- **Drug-Agent Interaction**: The impact of drug interactions on GAMMAPLEX has not been studied. If GAMMAPLEX is given concomitantly with any other drug, the potential for drug interaction or additive effects should be considered.

**THERAPEUTIC USES**

- **Treatment of Chronic Immune Thrombocytopenic Purpura**: GAMMAPLEX is designed to replace missing antibodies in patients with chronic immune thrombocytopenic purpura. It is also used in the treatment of primary humoral immunodeficiency.

**OVERDOSAGE**

Doses, and administer GAMMAPLEX 5.1, 5.2 [see Clinical Studies (10.3)].

**CLINICAL STUDIES**

- **Treatment of Primary Humoral Immunodeficiency**: In this study, PK bioequivalence was used as a surrogate marker for efficacy. Nevertheless, an **IBR**: Infectious bovine rhinotracheitis, bovine herpes virus model for enveloped DNA viruses including hepatitis B virus and human papilloma virus. **NA**: Not applicable, solvent detergent step is limited to the inactivation of enveloped viruses. **PER**: Pearson’s correlation coefficient. **Tmax** = time at which Cmax was apparent (corrected for baseline concentration). **CV**: Coefficient of variation.

**Efficacy Analysis of GAMMAPLEX**

- **Efficacy**: Efficacy analyses included the duration of response, and changes in the incidences of bleeding or hemorrhage. At Day 14, 96% of patients had a response. The duration of response for each product and this rate was achieved by all adult subjects. In this study, PK bioequivalence was used as a surrogate marker for efficacy. Nevertheless, an **IBR**: Infectious bovine rhinotracheitis, bovine herpes virus model for enveloped DNA viruses including hepatitis B virus and human papilloma virus. **NA**: Not applicable, solvent detergent step is limited to the inactivation of enveloped viruses. **PER**: Pearson’s correlation coefficient. **Tmax** = time at which Cmax was apparent (corrected for baseline concentration). **CV**: Coefficient of variation.

**CONTRAINDICATIONS**

- **Contraindications**: GAMMAPLEX is contraindicated in patients with known hypersensitivity to GAMMAPLEX or its components.

**WARNINGS**

- **Risk of Hypersensitivity Reactions**: GAMMAPLEX may cause hypersensitivity reactions, including anaphylaxis, in susceptible individuals. This risk is increased in patients with a history of hypersensitivity reactions to GAMMAPLEX or its components. The manufacturer recommends that GAMMAPLEX be administered with close monitoring for any signs of anaphylaxis or other adverse reactions.

**PRECAUTIONS**

- **General**: Patients should be monitored for signs of infection, inflammation, or other adverse reactions during and after therapy with GAMMAPLEX. The use of GAMMAPLEX should be discontinued if any adverse reactions are observed.

**ADVERSE REACTIONS**

- **Adverse Events**: The most common adverse events reported during GAMMAPLEX treatment were injection-site reactions, headache, cough, and rhinitis. Other adverse events included nausea, vomiting, diarrhea, and abdominal pain. These events are typically mild to moderate in severity and generally resolve without treatment.

**MECHANISM OF ACTION**

- **Mechanism of Action in PI**: While the mechanism of action in PI has not been fully elucidated, GAMMAPLEX is believed to work by increasing the immune response against the viruses present in the treated individual. This increased immune response helps to clear the viruses from the bloodstream.

**PHARMACOKINETICS**

- **Pharmacokinetics in PI**: The pharmacokinetics of GAMMAPLEX in PI have not been fully elucidated. However, studies have shown that GAMMAPLEX is well-absorbed and rapidly distributed throughout the body. The drug has a short half-life, allowing for repeated dosing.

**CLINICAL STUDIES**

- **Clinical Studies in PI**: In clinical studies, GAMMAPLEX showed efficacy in treating infections associated with PI. The drug was well-tolerated, with the most common adverse events being injection-site reactions and minor changes in blood count and liver function tests.

**INTERACTIONS**

- **Drug-Agent Interaction**: The impact of drug interactions on GAMMAPLEX has not been studied. If GAMMAPLEX is given concomitantly with any other drug, the potential for drug interaction or additive effects should be considered.

**SIDE EFFECTS**

- **Side Effects**: Side effects of GAMMAPLEX are generally mild to moderate in severity and are typically related to the injection site. They include pain, redness, and swelling at the injection site. However, these side effects are usually short-lived and do not require discontinuation of therapy.

**PATIENT INFORMATION**

- **Patient Information**: Patients should be informed about the potential side effects of GAMMAPLEX and what to do in case of an allergic reaction. They should also be advised to report any signs of infection or inflammation to their healthcare provider immediately.

**DISPENSATION**

- **Dispensation**: GAMMAPLEX is dispensed in a refrigerated container and should be administered within 24 hours of opening. The drug should be administered at a temperature of 2° to 8°C (36° to 46°F).