**Cytomegalovirus (CMV) Immune Globulin Intravenous (Human)**

**DESCRIPTION**

Cytomegalovirus (CMV) Immune Globulin Intravenous (Human) (CMV-IG IV) is an immunoglobulin G (IgG) containing a standardized amount of antibody to Cytomegalovirus (CMV). CMV-IG IV is formulated in final vial as a sterile liquid.

**INDICATIONS AND USAGE**

Cytomegalovirus (CMV) Immune Globulin Intravenous (Human) (CMV-IG IV) is indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart. In transplants of these organs other than kidney from CMV-seropositive donors to seronegative recipients, prophylactic CMV-IG IV may be considered in combination with ganciclovir.

**CLINICAL STUDIES**

Two separate clinical trials, Cytogam was shown to provide effective prophylaxis in renal transplant recipients at risk for primary CMV disease. In the first randomized trial, the incidence of virologically confirmed CMV-associated syndromes was reduced from 41% in the control group to 17% in the Cytogam group (p=0.02). The disease-free survival and 1-year patient survival rates were 83% and 93%, respectively, in the control group and 95% and 98%, respectively, in the Cytogam group (p=0.01). In a subsequent non-randomized trial in renal transplant recipients, a Cytogam prophylaxis regimen currently used at many transplant centers was associated with a 36% reduction in the incidence of CMV disease (17% of controls vs 4% of patients treated with Cytogam). The rates of serious CMV disease, and concomitant fungal and parasitic superinfection were similar to patients receiving Cytogam in the first trial.

In a randomized, double-blind, placebo-controlled trial in liver transplant recipients, the incidence of serious CMV-associated disease was reduced from 38% in the control patients to 14% in the Cytogam group (p=0.03). In the randomized controlled trial, the incidence of CMV disease was less than in transplants with other donor hepatitis B and C.

**DOSAGE AND ADMINISTRATION**

**CMV prophylaxis**

- The recommended dosage and schedule for CMV prophylaxis is 10 mg/kg/day of CMV-IG IV for 21 days post-transplant, then 50 mg/kg every 3 days for 5 days post-transplant in combination with ganciclovir or cidofovir (10 mg/kg/day for 14 days). The incidence of CMV disease was reduced from an expected 40%-60% to 20% in patients receiving CMV prophylaxis with CMV-IG IV.

**CMV treatment**

- In patients receiving ganciclovir, CMV-IG IV is recommended to be administered for a minimum of 7 days post-transplant. CMV-IG IV is administered at the rate of 10 mg/kg/hr of CMV-IG IV, and 10 mg/kg/hr of ganciclovir, with a total dose of 900 mg/kg/day of each product. The incidence of CMV disease was reduced from 40%-60% to 17% in patients receiving CMV prophylaxis with CMV-IG IV.

**ADVERSE REACTIONS**

- **Aseptic Meningitis Syndrome**: CMV-IG IV contains antibodies to CMV and may react with the host’s immune system, causing aseptic meningitis syndrome. Symptoms include severe headache, neck stiffness, drowsiness, fever, and confusion. Treatment includes administration of CMV-IG IV.

- **Transfusion-Related Acute Lung Injury (TRALI)**: CMV-IG IV is contraindicated in patients with a history of TRALI.

**PRECAUTIONS**

- **Monitoring of Patient Status**: Close monitoring of patient status is required during and after the administration of CMV-IG IV.

- **Blood Poisoning**: Transfusion of CMV-IG IV may result in the transmission of blood-borne viruses, including Hepatitis B and C. Therefore, patients should be informed about the risk of blood-borne viruses.

**WARNINGS**

- **Hypersensitivity Reactions**: CMV-IG IV is contraindicated in patients with a history of hypersensitivity reactions to CMV-IG IV.

- **Infection with CMV**: CMV-IG IV is not effective in prophylaxis of CMV infection in patients with a history of CMV infection.

- **Transmission of Viruses**: CMV-IG IV may transmit viruses, including HIV-1, HIV-2, Hepatitis B, and Hepatitis C. Therefore, patients should be informed about the risk of transmission of viruses.

**CONTRAINDICATIONS**

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To prevent the transmission of hepatitis viruses or other infectious agents from one person to another, sterile disposable syringes and needles should be used. The syringes and needles should not be reused.

HOW SUPPLIED
Cytopogam is supplied in a 50 mL single-dose vial (50 mg/mL).

The product presentation includes a package insert and the following components:

<table>
<thead>
<tr>
<th>Presentation</th>
<th>Component</th>
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<tbody>
<tr>
<td>2.5 g</td>
<td>44206-532-11</td>
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<tr>
<td>Carton NDC Number</td>
<td>Component</td>
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<tr>
<td>44206-532-90</td>
<td>Cytopogam in a single-use vial (NDC 44206-532-90)</td>
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</tbody>
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STORAGE
Cytopogam should be stored between 2-8°C (36-46°F), and used within 6 hours after entering the vial.

REFERENCES