Cytomegalovirus Immune Globulin Intravenous (Human) (IGIV) is indicated for the prophylaxis of cytomegalovirus disease against Cytomegalovirus (CMV). In the case of persons who may be exposed to CMV, Cytogam can raise the relevant antibodies to levels sufficient to attenuate or reduce the incidence of serious CMV disease.

CLINICAL STUDIES
Clinical studies have shown a 50% reduction in primary CMV disease in renal transplant patients given CMV-IGIV and a 56% reduction in serious CMV disease in liver transplant patients given CMV-IGIV. CMV-IGIV prophylaxis was associated with increased survival in liver transplant patients.

Ham et al.13 used CMV-IGIV with a dosage schedule of 150 mg/kg CMV-IGIV within 72 hours of transplant; 100 mg/kg CMV-IGIV was administered to seronegative donors in 1/4 of the liver transplant patients studied in this randomized controlled trial and a subsequent open-label trial7, the one serious CMV-associated disease included CMV disease in 2 or more organs, CMV pneumonia, or CMV-associated superinfections were not seen in globulin recipients but occurred in 20% of controls (P = 0.05). Serious CMV disease was reduced from 46% to 13%. There was a concomitant but not statistically significant reduction in the incidence of CMV pneumonia (17% of controls as compared with 4% of globulin recipients). There was no effect on rates of viral isolation or seroconversion although the rate of viremia was less in Cytogam recipients. In a subsequent non-randomized trial in renal transplant recipients, 125 mg/kg of CMV-IGIV was administered to 88% of CMV seronegative recipients. Surviving kidney recipients of a liver from a CMV seropositive donor. The incidence of serious CMV disease in the Cytogam group was less than 10%, whereas in the control group, the incidence was 20%.

Recent studies of combined prophylaxis with CMV-IGIV and ganciclovir have shown reductions in the incidence of serious CMV disease in CMV seronegative recipients of CMV seropositive donors and in 1/4 of the liver transplant patients studied in this randomized controlled trial and a subsequent open-label trial7, the one year survival of the 72 control patients was 72% versus 86% in the 90 recipients of CMV-IGIV (P = 0.03). In the randomized controlled trial, the reduction in serious CMV-associated disease in CMV seronegative recipients of liver from a CMV seropositive donor was 10% (95% confidence interval, 3% to 17%) and was only that of patients with other donor characteristics. The one year survival of 125 mg/kg of CMV-IGIV was administered to 88% of CMV seronegative recipients. Surviving kidney recipients of a liver from a CMV seropositive donor. The incidence of serious CMV disease in the Cytogam group was less than 10%, whereas in the control group, the incidence was 20%.

Smyth14 using the CMV-IGIV dosage schedule listed under DOSAGE AND ADMINISTRATION section in combination with ganciclovir (10 mg/kg/day for 14 days) reduced the incidence of serious CMV disease in D+R- liver transplant recipients receiving placebo or one drug at 16/47 (34%) to 3/41 (7%) in patients receiving both drugs for prophylaxis.

Martin15 using CMV-IGIV 100 mg/kg every two weeks for six weeks followed by 50 mg/kg every two weeks for a final dose at week 16, in combination with ganciclovir 10 mg/kg/day for 14 days after transplantation, observed severe CMV disease in 1/14 (7%) of CMV seronegative recipients of a kidney from a CMV seropositive donor. In 1/14 (7%) of CMV seronegative recipients of a kidney from a CMV seropositive donor and in 1/12 (8%) of CMV seronegative recipients of a liver from a CMV seropositive donor. The incidence of serious CMV disease with combined CMV-IGV and ganciclovir prophylaxis was lower than previous experience with single drug prophylaxis.

Valentine and Lukant12 compared prophylaxis with CMV-IGIV (biweekly for three months) in combination with ganciclovir prophylaxis (IV at 5 mg/kg twice a day for the initial 14 days post transplant, then at 6 mg/kg through day 28) in 16 CMV seronegative recipients of a kidney from a CMV seropositive donor and in 1/12 (8%) of CMV seronegative recipients of a liver from a CMV seropositive donor. The incidence of serious CMV disease with combined CMV-IGV and ganciclovir prophylaxis was lower than previous experience with single drug prophylaxis.

Cytogam should not be used in individuals with a history of a prior severe reaction associated with the administration of this or other human immunoglobulin preparations. Persons with selective immunoglobulin A deficiency have the potential for developing antibodies to immunoglobulin A and could have anaphylactic reactions to subsequent administration of blood products that contain immunoglobulin A, including Cytogam.
Liver, Pancreas, Lung, Heart

Carton NDC Number
Cytogam in a single-use vial [NDC 44206-532-90]

The maximum recommended total dosage per infusion is 150 mg Ig/kg, administered according to the following

DOSAGE AND ADMINISTRATION

Although few data are available, clinical experience with other immunoglobulin preparations suggests that the major

ADVERSE REACTIONS

Minor reactions such as flushing, chills, muscle cramps, back pain, fever, nausea, vomiting, arthralgia, and wheezing were

In the absence of prospective data, recommended doses should not be exceeded and the concentration and infusion rate selected should be the minimum practicable.

Protection against the transmission of hepatitis viruses or other infectious agents from one person to another, sterile disposable

HOW SUPPLIED

Cytogam is supplied in a 50 mL single-dose vial (50 mg/mL).

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

Presentation Carton NDC Number Component
2.5 g 44206-532-11 Cytogam in a single-use vial [NDC 44206-532-90]

STORAGE

Cytogam should be stored between 2°C-8°C (36-46°F), and used within 6 hours after entering the vial.

REFERENCES


