Geriatric:
In patients over age 65 or in any patient at risk of developing renal insufficiency, do not exceed the recommended dose, and infuse minimum infusion rate practicable.

How Supplied:
Aqueous solution containing 5% IgG in 100 mL bottle.

Preparation and Handling :
Inspect the product visually for particulate matter and discoloration prior to administration.

Allow refrigerated product to come to room temperature before use.

Do not use if the solution is turbid or tampered.

Do not shake. Do not mix with other products.

Do not use normal saline as a diluent. If dilution is desired, 5% dextrose in water (D5W) should be used as a diluent.

Storage and Shelf Life:

Store the bottle in original carton between 2^{o}C to 8^{o} C.

Protect from light. Do not freeze. Keep out of reach of children.

Immuglo 5% is stable for three years when stored at recommended storage conditions.

Manufactured and Marketed by:

Hemarus Therapeutics Limited

Survey No. 222P, Turkapally Village, Shameerpet Mandal , R.R. DIST,- 500 078, A.P. India

HUMAN NORMAL IMMUNOGLOBULIN FOR IV USE 5% I.P.

immuglo™
HUMAN NORMAL IMMUNOGLOBULIN 5% I.P. (50mg/mL)

WARNING :
Patients at risk of renal dysfunction or failure, administer Human Normal Immunoglobulin for IV Use 5% I.P. at the minimum rate of infusion possible.

Renal dysfunction and acute failure occur more commonly in patients receiving IVIG products containing sucrose. IMMUGLO 5% liquid does not contain sucrose.

Description

Human Normal Immunoglobulin for Intravenous Use I.P. (IVIG) is a sterile, 5% liquid preparation of Immunoglobulin G (IgG) purified from a large pool of human plasma for fractionation. The product is manufactured by a series of chromatography based purification process. The manufacturing process includes dedicated viral inactivation and removal steps such as ***treatment with TNBP and Triton X-100, low pH treatment and Nanofiltration.***

Composition:

Each 100 mL bottle of Immuglo 5% contains 5 g(50 g /L) of Human Normal Immunoglobulin for IV Use.

Stabilizer Maltose :10%
IgA content: ≤ 4 mg/L
IgM content : ≤ 0.1mg/L
Contains no preservatives.

Immunoglobulin G sub class distribution is normal.
Source: Human Plasma for Fractionation that is , non –reactive for HBs Antigen,, HCV, HIV 1&2 antibodies and negative for the viruses, HIV1 &2, HCV and i.e. HBV using NAT.

Clinical Pharmacology:

Immunoglobulin G (IgG) is a major Isotype of antibodies present in the human blood and extracellular fluid allowing it to control infection of body tissues.
IgG has several immunomodulating activities that include modulation of complement activation; suppression of idiotypic antibodies; saturation of Fc receptors on macrophages; and suppression of various inflammatory mediators, including cytokines, chemokines, and metalloproteinases. The Fc region of IgG facilitates interaction with and signaling through Fc receptors on phagocytes, B cells, and other cells and with Fc-binding plasma proteins (eg, components of the complement system).

Indications:

Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies1, 2.

Immunoglobulin G preparations are indicated in several clinical conditions. An approved list of clinical conditions where is indicated, is as under:

- Kawasaki Syndrome
- Idiopathic Thrombocytopenic Purpura
- B-cell Chronic lymphocytic leukemia
- Paediatric HIV 1 infection
- Hemopoietic stem cell transplantation in elderly

Dosage and Administration:

Intravenous Immunoglobulin G for a patient should be adjusted according to clinical response.
The following are dosage schedule guidelines:

Indication	Dose
Replacement therapy in Primary Immunodeficiency	Starting dose:0.4-0.8 g/kg followed by 0.2-0.8 g/kg every 2-4 weeks to obtain IgG trough level of at least 4-6 g/L
Replacement therapy in Secondary immunodeficiency	0.2-0.4 g/kg every 3-4 weeks to obtain IgG trough level of at Ieast 4-6 g/L
Allogeneic Bone marrow Transplantation (1) Treatment of infections and prophylaxis of graft versus host disease (2) Persistent lack of antibody production	0.5 g/kg every week from day 7 up to 3 months after transplantation. 0.5 g/kg every month until antibody levels return to normal
Guillain Barré syndrome	0.4 g /kg/d for 3 -7 days
Kawasaki disease	1.6 - 2 g/kg in several doses for 2 - 5 days in association with acetylsalicylic acid or 2 g/kg in one dose in association with acetylsalicylic acid
Pediatic HIV	0.2 - 0.4 g/kg every 3 - 4 weeks
Idiopathic Thrombocytopenic Purpura	0.8 - 1 g/kg on day 1, possibly repeated once within 3 days or 0.4 g/kg/d for 2 - 5 days

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Once open the contents must not be used more than four hours. Discard unused portion.

Contraindications:

- Anaphylactic or severe systemic hypersensitivity reactions to Human Immunoglobulin
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity.

Warnings and Precautions:

IgA deficient patients with antibodies to IgA are at greater risk of developing severe hypersensitivity and anaphylactic reaction.

Monitor renal function, including blood urea nitrogen, serum creatinine, and urine output in patients at risk of acute renal failure.

Hyperproteinemia, increased serum viscosity and hyponatremia may occur.

Thrombotic events may occur. Monitor patients with known risk factors for thrombotic events; consider baseline assessment of blood viscosity for those at risk for hyperviscosity.

Aseptic Meningitis Syndrome (AMS) may occur.

Hemolytic anemia can develop. Monitor for clinical signs and symptoms of hemolysis and hemolytic anaemia.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury.)

Adverse Reactions

Undesirable effects from IVIG occur in less than 5% of patients. The most common adverse effects occur soon after infusions and can include headache, flushing, chills, myalgia, wheezing, tachycardia, lower back pain, nausea, and hypotension. If this happens during an infusion, the infusion should be slowed or stopped. If symptoms are anticipated, a patient can be premedicated with antihistamines and intravenous hydrocortisone.

Over Dosage
Overdose may lead to fluid overload and hyperviscosity. Patients at risk of complications of fluid overload and hyperviscosity include elderly patients and those with cardiac or renal impairment.

Use in Special Population :

Pregnancy
Should be given to a pregnant woman only if clearly needed.