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: ≤ 0.1 mg/L
Contains no preservatives.
Immunoglobulin G subclass 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 e.g. HBV using NAT.

**Clinical Pharmacology:**
Immune Globulin (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 idiotype antibodies; saturation of Fc receptors on macrophages; and suppression of various inflammatory mediators, including cytokines, chemokines, and metalloproteinases. The Fe 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).

**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.

**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°C to 8°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.

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

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**Manufactured and Marketed by:**
Hemurus Therapeutics Limited
Survey No. 222P, Turkapally Village, Shameerpet Mandal, R.R. DIST., 500 078, A.P. India
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Once open the container 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.

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.

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 immunodeficiencies.

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:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
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<tbody>
<tr>
<td>Replacement therapy in</td>
<td></td>
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<tr>
<td>Primary Immunodeficiency</td>
<td>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</td>
</tr>
<tr>
<td>Replacement therapy in Secondary</td>
<td>0.2-0.4 g/kg every 3-4 weeks to obtain IgG trough level of at least 4-6 g/L</td>
</tr>
<tr>
<td>immunodeficiency</td>
<td></td>
</tr>
<tr>
<td>Allogeneic Bone marrow Transplantation</td>
<td>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</td>
</tr>
<tr>
<td>Guillain Barre syndrome</td>
<td>0.4 g/kg/d for 3 - 7 days</td>
</tr>
<tr>
<td>Kawasaki disease</td>
<td>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</td>
</tr>
<tr>
<td>Pediatric HIV</td>
<td>0.2 - 0.4 g/kg every 3 - 4 weeks</td>
</tr>
<tr>
<td>Idiopathic Thrombocytopenic Purpura</td>
<td>0.8 - 1 g/kg on day 1, possibly repeated once within 3 days or 0.4 g/kg/d for 2 - 5 days</td>
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Intravenous Immunoglobulin G for a patient should be adjusted according to clinical response. The following are dosage schedule guidelines: