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

immuglo®

HUMAN NORMAL IMMUNOGLOBULIN 5% I.P. (50 g/L)

0.5 g / 1.0 g / 2.5 g / 5.0 g

Solvent/Detergent treated (S/D) and Nanofiltered (NF)

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 product containing sucrose.
Note: IMMUGLO 5% S/D and NF 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 chromatography based purification process. The manufacturing process includes dedicated viral inactivation and removal steps such as treatment with TNBP and Triton X-100 (S/D), low pH treatment and Nanofiltration.

COMPOSITION

Human Normal Immunoglobulin - 50 g/L
Stabilizer: Maltose 10%
Immunoglobulin G $\geqslant$ 95%
IgA content $\leqslant$ 30 mg/L
Contains no preservatives.

Immunoglobulin G subclasses: The distribution for the four IgG subclasses are 65.9% $\pm$ 5.6% IgG_1, 25.2% $\pm$ 5.8% IgG_2, 5.5% $\pm$ 3.0% IgG_3, 2.5% $\pm$ 1.8% IgG_4.

Source: Human Plasma for Fractionation that is, non-reactive for HBsAg, HCV, HIV 1&2 antibodies and negative for HIV 1&2, HCV and 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 (e.g. components of the complement system).

INDICATIONS

Indicated as replacement therapy for primary humoral immunodeficiency (PID) 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 1,2.

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

- Kawasaki syndrome
- Idiopathic Thrombocytopenic Purpura
- B-cell Chronic Lymphocytic Leukemia
- Pediatric HIV 1 infection
- Hemopoietic stem cell transplantation in elderly patients

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 least 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 Barre 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.
Pediatric 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.
Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP)	Starting dose : 2 g/kg in divided doses over 2-5 days. Maintenance dose : 1 g/kg every 3 weeks over 1-2 days
Multifocal Motor Neuropathy (MMN)	Starting dose : 2 g/kg over 2-5 consecutive days Maintenance dose : 1 g/kg every 2-4 weeks. or 2 g/kg every 4-8 weeks over 2-5 days

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

Once open, the contents must be used within four hours. Discard unused portion.

Rate of Administration

It is recommended that a 5% solution be initially infused at a rate of 30 mg/kg/hour for the first 30 minutes; if tolerated, advance to 60 mg/kg/hour for the second 30 minutes; and if further tolerated, advance to 120 mg/kg/hour for the third 30 minutes. Thereafter the infusion can be maintained at a rate up to, but not exceeding, 200 mg/kg/hour.

CONTRAINDICATIONS

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

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

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

Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent."

ADVERSE REACTIONS

Undesirable effects from IVIG occur in less than 5% of patients. The most common adverse effects occur soon after infusion 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.

Geriatric

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

HOW SUPPLIED

Immuglo 5% is supplied as 0.5 g, 1.0 g, 2.5 g and 5.0 g of Human Normal Immunoglobulin in single use bottles.

Pack Size	10 mL	20 mL	50 mL	100 mL
Protein	0.5 g	1.0 g	2.5 g	5.0 g

PREPARATION AND HANDLING

Allow refrigerated product to come to room temperature before use.

Do not use if the solution is turbid.

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 its original carton between 2°C and 8°C.

Protect from light.
Do not freeze.

Keep out of reach of children.

Immuglo 5% S/D and NF is stable for three years when stored at recommended storage conditions.

Manufactured and Marketed by:

ICHOR
Biologics Pvt. Ltd.
Sy. No. 222 P, Turkapally Village,
Shameerpet Mandal,
Medchal-Malkajgiri Dist.,
Telangana - 500 078, India

139 x 215mm
New finalized file
0.5 g / 1.0 g / 2.5 g / 5.0 g

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