SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

V-IMMUNE, human normal immunoglobulin solution 50 g/Lit (5%)

2. Qualitative and quantitative composition

V-Immune, Human Normal Immunoglobulin for Intravenous use 5% Solution is a sterile, non-pyrogenic preparation of human normal immunoglobulin for intravenous administration.

Each 100mL contains 5g of human normal immunoglobulin and is prepared from the qualified human plasma.

For the full list of excipients see section 6.1

3. Pharmaceutical form

Solution for Injection.

4. Clinical particulars

4.1 Therapeutic indications

Primary Immunodeficiency Diseases

V-IMMUNE is indicated for the treatment of primary immune deficient states, such as: congenital agammaglobulinemia, common variable immunodeficiency, Wiskott- Aldrich syndrome, and severe combined immune deficiencies.

B-cell Chronic Lymphocytic Leukemia (CCL)

V-IMMUNE is indicated for prevention of bacterial infections in patient with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL).

Idiopathic Thrombocytopenic Purpura (ITP)

V-IMMUNE is indicated when a rapid rise in platelet count is needed to prevent and/or to control bleeding in a patient with Idiopathic Thrombocytopenic Purpura.

Kawasaki Syndrome

V-IMMUNE is indicated for the prevention of coronary artery aneurysms associated with Kawasaki syndrome.

4.2 Dosage and method of administration

For intravenous use only Preparation and Handling

- V-IMMUNE is a clear or slightly opalescent, colorless solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the solution is cloudy or turbid, of if it contains particulate matter.
- Do not freeze, and do not use any solution that has been frozen.
- Do not shake.
- V-IMMUNE should be at room temperature at the time of administration.
- Do not use V-IMMUNE beyond the expiration date on the product label.
- The V-IMMUNE is for single use only. Dispose of partially used or unused product.
- **Infuse V-IMMUNE using a separate infusion line.**

- **Do not mix with other intravenous medications (including normal saline) or other IVIg products.**

DOSAGE

As there are significant differences in the half-life of IgG among patients with primary immunodeficiency, the frequency and amount of immunoglobulin therapy may vary from patient to patient. The proper amount can be determined by monitoring clinical response.

The recommended dose of IVIg for patients with primary immunodeficiency is 300 to 600 mg/kg administered every 3 to 4 weeks. Adjust the dosage over time to achieve the desired serum through levels clinical responses. If a patient misses a dose, administer the missed dose as soon as possible, and then resume scheduled treatments every 3 or 4 weeks, as applicable.

Idiopathic Thrombocytopenic Purpura (ITP)

The usual dosage for the treatment of acute and chronic ITP is 200-400 mg/kg daily given for 5 consecutive days. The additional doses are discontinued if an adequate response does not occur.

Kawasaki Syndrome

The usual dosage is 400 mg/kg daily for 5 consecutive days.

Infusion rate

0.01 – 0.02 mL/kg/min for the first 30 minutes and increase upto 0.06 mL/kg/min if there are no adverse effects.

4.3 Contraindications

V-IMMUNE is contraindicated in patients with selective IgA deficiency where the IgA deficiency is the only abnormality of concern. Patients may experience severe hypersensitivity reactions or anaphylaxis in the setting of detectable IgA levels following infusion of V-IMMUNE. The occurrence of severe hypersensitivity reactions or anaphylaxis under such conditions should prompt consideration of an alternative therapy.

4.4 Special warnings and precautions for use

Hypersensitivity

Severe hypersensitivity reactions may occur. In case of hypersensitivity, discontinue V-IMMUNE infusion immediately and institute appropriate treatment. Medication such as epinephrine should be available for immediate treatment of acute hypersensitivity reactions.

Renal Dysfunction/Failure

Acute renal dysfunction/failure, osmotic nephropathy, and death may occur upon use of human IVIg products. Ensure that patients are not volume depleted before administering V-IMMUNE. In patients who are at risk of developing renal dysfunction, because of pre-existing renal insufficiency or predisposition to acute renal failure (such as diabetes mellitus, hypovolemia, overweight, use of concomitant nephrotoxic medicinal products or age of >65 years), administer V-IMMUNE™ at the minimum infusion rate.

Hyperproteinemia, Increased Serum Viscosity, and Hyponatremia
Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IVIg therapy. It is critical to clinically distinguish true hyponatremia from a pseudohyponatremia that is associated with or causally related to hyperproteinemia with concomitant decreased calculated serum osmolality or elevated osmolar gap, because treatment aimed at decreasing serum free water in patients with pseudohyponatremia may lead to volume depletion, a further increase in serum viscosity, and possible predisposition to thrombotic events.

Thrombotic Events
Thrombotic events may occur following treatment with V-IMMUNE and other IVIg products. Patients at risk include those with history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization, and/or known/suspected hyperviscosity. For patients judged to be at risk of developing thrombotic events, administer V-IMMUNE at the minimum rate of infusion.

Aseptic Meningitis Syndrome (AMS)
AMS may occur infrequently with IVIg treatment. AMS usually begins within several hours to 2 days following IVIg treatment. Discontinuation of IVIg treatment has resulted in remission of AMS within several days without sequelae. AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IVIg.

Hemolysis
IVIg products can contain blood group antibodies that may act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing positive direct antiglobulin reaction and, rarely, hemolysis. Delayed hemolytic anemia can develop subsequent to IVIg therapy due to enhanced RBC sequestration and acutehemolysis, consistent with intravascular hemolysis, has been reported.

Transfusion-related Acute Lung Injury (TRALI)
Noncardiogenic pulmonary edema may occur in patients following IVIg treatment. TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Symptoms typically appear within 1 to 6 hours following treatment. Monitor patients for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and the patient's serum. TRALI may be managed using oxygen therapy with adequate ventilatory support.

Transmissible Infectious Agents
V-Immune is made from human plasma. Based on effective donor screening and product manufacturing processes, V-IMMUNE carries an extremely remote risk of transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), a viral disease is considered to be extremely remote.

Monitoring: Laboratory Tests
- Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of V-IMMUNE and at appropriate intervals thereafter.

- Because of the potentially increased risk of thrombosis, consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies.
- If signs and/or symptoms of hemolysis are present after an infusion of V-IMMUNE, perform appropriate laboratory testing for confirmation.
- If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and patient's serum.

Information for patients
Patients should be instructed to immediately report symptoms of decreased urine output, sudden weight gain, fluid retention/edema, and/or shortness of breath (which may suggest kidney damage) to their physician.

4.5 Interaction with other medicinal products and other forms of interaction No specific interactions of human normal immunoglobulin with other medicinal products are known.

4.6 Pregnancy and lactation Pregnancy Category C:
Animal reproduction studies have not been conducted with V-IMMUNE. It is also not known whether V-IMMUNE can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. V-IMMUNE should be given to a pregnant woman only if clearly needed.

4.7 Effects on ability to drive and use machines
No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects
The following is a list of adverse reactions that have been identified and reported during the pose-approval use of IVIg products:

Infusion reactions: Hypersensitivity (e.g., anaphylaxis), headache, diarrhea, tachycardia, fever, fatigue, dizziness, malaise, chills, flushing, utricaria or other skin reactions, wheezing or other chest discomfort, nausea, vomiting, rigors, back pain, myalgia, arthralgia, and changes blood pressure.

Renal: Acute renal dysfunction/failure, osmotic nephropathy

Respiratory: Apnea, Acute Respiratory Distress Syndrome (ARDS), TRALI, cyanosis, hypoxemia, pulmonary edema, dyspnea, bronchospasm

Cardiovascular: Cardiac arrest, thromboembolism. vascular collapse, hypotension

Neurological: Coma, loss of consciousness, seizures, tremor, aseptic meningitis Syndrome

Integumentary: Stevens-Johnson syndrome, epidermolysis, erythema multiforme, dermatitis (e.g., bullous dermatitis)

Hematologic: Pancytopenia, leucopenia, hemolysis, positive direct antiglobulin (Coombs') test

Gastrointestinal: Hepatic dysfunction, abdominal pain

General/Body as a whole: Pyrexia, rigors

Reporting of suspected adverse reactions:
Healthcare professionals are requested to report any suspected adverse reactions via the national Pharmacovigilance Electronic Reporting Systems to the respective national regulatory authorities.

4.9 Overdose: Consequences of an overdose are not known.

5. Pharmacological properties
V-IMMUNE, Human Normal Immunoglobulin intravenous, contains a broad spectrum of IgG antibodies against bacterial and viral agents that are capable of opsonization and neutralization of microbes and toxins. Peak levels of IgG are reached immediately after infusion of V-IMMUNE. It has been shown that, after infusion, exogenous IgG is distributed relatively rapidly between plasma and extravascular fluid until approximately half is partitioned in the extravascular space. Therefore, a rapid initial drop in serum IgG levels is to be expected. As a class, it is reported that IgG survives longer in-vivo than other serum proteins.

5.1 Preclinical safety data
Human normal immunoglobulin is a preparation of human plasma proteins, so safety testing in animals is not particularly relevant to the safety of use in man. However, published studies reported that acute toxicity studies in rat and mouse showed no minimum lethal dose with the clinical strength product used at approximately 1,250 mg/kg. This is equivalent to approximately 10 times the dose in man. Repeated dose testing is impracticable due to induction of, and interference with antibodies, to human protein. Clinical experience provides no evidence of tumourigenic and mutagenic effects.

6. Pharmaceutical particulars
6.1 List of excipients

Maltose
Water for Injection

6.2 Incompatibilities
All the excipients and the packing materials used are compatible to the drug product.

6.3 Shelf life
3 years from the date of manufacturing.

6.4 Special precautions for storage
Store at 2-8°C. Do not freeze. Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Human Normal Immunoglobulin is supplied in USP type I glass vials, stoppered with rubber stoppers/rubber closures/ Elastomeric rubber closures and sealed with Mist Grey color aluminum flip-off seals.

6.6 Special precautions for disposal and other handling

V-Immune Solutions must not be diluted with water for injections as this may cause haemolysis in recipients. Any unused medicinal product or waste material should be disposed of in accordance with local regulatory requirements.

7. Marketing authorization holder

Virchow Healthcare Pvt. Ltd.

8. Marketing authorization number(s)

H2026/CTD7212/14156

9. Date of first authorization/renewal of the authorization

February 18 2026

10. Date of revision of the text

February 18 2026

11. Legal category

Prescription only Medicine

End of the Document