SUMMARY OF PRODUCT CHARACTERISTICS

V-IMMUNE, Human Normal Immunoglobulin Solution for Intravenous Administration BP 5% (50 g/L)

1. NAME OF THE MEDICINAL PRODUCT

V-IMMUNE, Human Normal Immunoglobulin Solution for Intravenous Administration BP 5% (50 g/L)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml contains 5 g of Human Normal Immunoglobulin BP (IgG), prepared from qualified, screened and virus-inactivated human plasma pools.

Concentration: 50 g/L (5% w/v).

The distribution of IgG subclasses is similar to that in normal human plasma.

Excipients with known effect:

None

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.

Clear or slightly opalescent, colourless or pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Replacement therapy

Primary immunodeficiency syndromes such as: congenital agammaglobulinaemia and hypogammaglobulinaemia; common variable immunodeficiency (CVID); Wiskott-Aldrich syndrome; severe combined immunodeficiencies (SCID).

Secondary hypogammaglobulinaemia in patients with B-cell chronic lymphocytic leukaemia (CLL) in whom prophylactic antibiotics have failed or are contraindicated; multiple myeloma patients who fail to respond to pneumococcal immunisation.

Immunomodulation

Primary immune thrombocytopenia (ITP) when a rapid increase in platelet count is required to control or prevent bleeding, or prior to surgery.

Kawasaki disease: prevention of coronary artery aneurysms in conjunction with aspirin.

Guillain-Barré syndrome; Chronic inflammatory demyelinating polyneuropathy (CIDP).

4.2 Posology and method of administration

General

V-IMMUNE is for intravenous (IV) use only. The dose and dosing schedule depends on the indication. Dosage may need to be individualised for each patient on the basis of clinical response and pharmacokinetic data such as serum IgG trough levels.

Replacement therapy — Primary immunodeficiency (PID)

Loading dose (if not previously treated): 0.4–0.8 g/kg body weight as a single infusion. Maintenance dose: 0.2–0.8 g/kg/month administered every 3–4 weeks. The dose and dosing interval should be adjusted to achieve a pre-dose (trough) serum IgG level of at least 5–6 g/L (or above the lower limit of normal for age).

Secondary immunodeficiency

0.2–0.4 g/kg every 3–4 weeks.

Primary immune thrombocytopenia (ITP)

Treatment course: 0.8–1 g/kg on day 1 (may be repeated once on day 3); or 0.4 mg/kg/day for 5 consecutive days. Treatment may be repeated if relapse occurs.

Kawasaki disease

2 g/kg administered as a single dose, in conjunction with aspirin.

Guillain-Barré syndrome / CIDP

0.4 g/kg/day for 5 consecutive days (total 2 g/kg). Maintenance in CIDP: 1 g/kg every 3 weeks or 0.5 g/kg for 2 consecutive days every 3 weeks.

Infusion rate

Initial rate: 0.01–0.02 ml/kg/min for the first 30 minutes. If well tolerated, the rate may be gradually increased to a maximum of 0.06 ml/kg/min. In patients receiving IVIg for the first time, or who have not received it for a prolonged period, the initial infusion rate should be slow and increased only if well tolerated.

Special populations

Elderly and patients at risk of renal impairment or thrombosis: The minimum practicable infusion rate should be used. Paediatric population: Dosing is the same as for adults, adapted by indication and body weight.

Method of administration

Intravenous infusion only. Must not be administered intramuscularly or subcutaneously.

4.3 Contraindications

- Hypersensitivity to human immunoglobulins or to any of the excipients listed in section 6.1.
- Selective IgA deficiency with anti-IgA antibodies, due to the risk of severe anaphylaxis.

4.4 Special warnings and precautions for use

Traceability

To improve traceability of biological medicinal products, the name and batch number of the administered product should be clearly recorded (or stated in the patient file).

Hypersensitivity reactions

Hypersensitivity reactions are rare. Anaphylaxis or anaphylactoid reactions may occur, especially in patients with IgA deficiency with anti-IgA antibodies and in patients with true hypersensitivity to immunoglobulins. The infusion must be discontinued immediately if blood pressure falls or anaphylaxis develops, and appropriate emergency treatment initiated (e.g. adrenaline). Patients should be monitored carefully for any symptoms throughout the infusion period.

Thrombosis

Thrombosis, including pulmonary embolism, deep vein thrombosis, myocardial infarction, stroke and arterial occlusion, has been reported following IVIg therapy. Risk factors include: advanced age, hypertension, diabetes, pre-existing vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders, prolonged periods of immobilisation, severe hypovolaemia and diseases which increase blood viscosity. In patients at risk, V-IMMUNE should be administered at the minimum practicable rate. Adequate hydration should be ensured before infusion. Patients should be monitored for signs and symptoms of thrombosis and assessed for hypercoaguability.

Renal impairment

Acute renal failure has been reported in patients receiving IVIg. In most cases, risk factors have been identified such as pre-existing renal insufficiency, diabetes, hypovolaemia, obesity, concomitant nephrotoxic medicinal products or age >65 years. Renal function and urine output should be monitored before the infusion and at appropriate intervals thereafter, especially in patients at higher risk. In patients at risk, V-IMMUNE should be administered at the minimum practicable rate and dose. Adequate hydration should be ensured prior to infusion.

Aseptic meningitis syndrome (AMS)

AMS has been reported with IVIg treatment. Discontinuation of IVIg treatment has resulted in remission of AMS within several days without sequelae. It occurs more frequently with high doses and/or rapid infusion.

Haemolytic anaemia

IVIg products may contain blood group antibodies that may act as haemolysins and induce in vivo coating of red blood cells with immunoglobulin, causing a positive direct antiglobulin test and, rarely, haemolysis. Haemolytic anaemia can develop after IVIg therapy. Patients should be monitored for clinical signs and symptoms of haemolysis.

Transfusion-related acute lung injury (TRALI)

Non-cardiogenic pulmonary oedema may occur. TRALI is characterised by severe respiratory distress, pulmonary oedema, hypoxaemia, normal left ventricular function and fever, usually within 1–6 hours after transfusion. If TRALI is suspected, V-IMMUNE should be stopped and appropriate treatment initiated.

Transmissible infectious agents

V-IMMUNE is manufactured from human plasma. Despite standard measures (donor screening, testing of individual donations and plasma pools, validated viral inactivation/removal steps), the risk of transmission of infectious agents — including novel and unrecognised agents — cannot be completely excluded. This also applies to prion diseases such as variant Creutzfeldt-Jakob disease (vCJD). The measures taken are considered effective against enveloped viruses such as HIV, HBV and HCV, and for non-enveloped viruses HAV and B19.

Effects on serology

After infusion of V-IMMUNE, the transitory rise of various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing. Passive transmission of anti-A and anti-B blood group antibodies may interfere with some serological methods.

4.5 Interaction with other medicinal products and other forms of interaction

Live attenuated virus vaccines:

IVIg may impair the efficacy of live attenuated virus vaccines such as measles, mumps and rubella. A period of at least 3 months should elapse before administration of live attenuated vaccines. In the case of measles, this impairment may persist for up to 1 year; patients should have their antibody status checked before revaccination.

Immunoglobulins should not be mixed with other medicinal products (see section 6.2).

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of V-IMMUNE for use in human pregnancy has not been established in controlled clinical trials. Immunoglobulins cross the placenta, increasingly so during the third trimester. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, the foetus or the neonate are to be expected. V-IMMUNE should be given to pregnant women only if clearly needed.

Breast-feeding

Immunoglobulins are excreted in breast milk and may contribute to the transfer of protective antibodies to the neonate. No harmful effects on the breast-fed infant are anticipated.

Fertility

No effects on fertility are anticipated based on clinical experience.

4.7 Effects on ability to drive and use machines

No effects on the ability to drive or use machines have been observed with V-IMMUNE. However, some adverse events (dizziness, headache) may temporarily affect the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

Adverse reactions associated with IVIg products include chills, headache, dizziness, fever, vomiting, nausea, arthralgia and moderate low back pain. Rarely, sudden hypotension and anaphylaxis may occur. Thromboembolic events, haemolytic reactions and TRALI have been reported.

System Organ Class	Adverse Reaction (frequency not known)
Immune system disorders	Hypersensitivity, anaphylaxis/anaphylactoid reactions including circulatory collapse
Nervous system disorders	Headache, dizziness, aseptic meningitis syndrome
Cardiac disorders	Tachycardia, myocardial infarction (thrombosis-related)
Vascular disorders	Hypotension, hypertension, thromboembolism (including DVT, pulmonary embolism, stroke)
Respiratory, thoracic and mediastinal	Dyspnoea, TRALI (transfusion-related acute lung injury)
Gastrointestinal	Nausea, vomiting, abdominal pain, diarrhoea
Skin and subcutaneous tissue	Rash, pruritus, urticaria, angioedema
Musculoskeletal	Arthralgia, back pain, myalgia

System Organ Class	Adverse Reaction (frequency not known)
Blood and lymphatic system	Haemolytic anaemia, positive direct antiglobulin test (Coombs test), transient neutropenia
Renal and urinary	Acute renal failure
General disorders	Chills, fever, fatigue, pain and reactions at infusion site

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose
Overdose may lead to fluid overload and hyperviscosity, particularly in patients at risk including elderly patients or patients with impaired cardiac or renal function. Patients should be monitored and managed with appropriate supportive therapy.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Immune sera and immunoglobulins: immunoglobulins, normal human, for intravascular administration. ATC code: J06BA02.

Human Normal Immunoglobulin contains mainly IgG with a broad spectrum of antibodies against infectious agents. It is prepared from pooled plasma from screened donors. The distribution of IgG subclasses (IgG1, IgG2, IgG3, IgG4) closely corresponds to that in native human plasma. In replacement therapy: the minimum effective serum IgG level is considered to be 5–6 g/L (pre-dose trough level). In immunomodulation: the mechanism is not fully elucidated but involves Fc receptor blockade, complement regulation, anti-idiotype antibody effects, and modulation of cytokine production and the activity of immune cells.

5.2 Pharmacokinetic properties
Following intravenous administration, V-IMMUNE is immediately and completely bioavailable in the circulation of the recipient. It is distributed relatively rapidly between plasma and extravascular fluid; equilibrium between intra- and extravascular compartments is reached after approximately 3–5 days. The half-life of IgG in immunodeficient patients is on average 3 weeks, with considerable inter-individual variation. IgG and IgG complexes are broken down in the reticuloendothelial system.

5.3 Preclinical safety data
Human Normal Immunoglobulin is a normal constituent of the human body. No conventional preclinical safety studies are required or relevant for this product class.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Maltose, water for injections.

6.2 Incompatibilities
V-IMMUNE must not be mixed with other medicinal products or added to any other infusion fluid. V-IMMUNE must not be mixed with immunoglobulins from other manufacturers.

6.3 Shelf life
3 years. Once opened, V-IMMUNE should be used immediately.

6.4 Special precautions for storage
Store at 2°C–8°C (in a refrigerator). Do not freeze. Protect from light. Keep out of the reach and sight of children.

6.5 Nature and contents of container

USP Type I glass vials with rubber closures and aluminium flip-off seals. Pack sizes: various (as licensed). Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

V-IMMUNE should be at room temperature or body temperature before use. The solution should be clear or slightly opalescent. Do not use solutions that are cloudy or contain deposits. Once a vial has been opened, the product should be used immediately. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

VIRCHOW HEALTHCARE PVT. LTD.

(Address to be confirmed from approved CTD dossier.)

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD7212/14156

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

19.02.2026

10. DATE OF REVISION OF THE TEXT

19.02.2026