Better Health, Brighter Future

Dear Colleagues,

Takeda is pleased to announce KIOVIG® (Normal immunoglobulin (Human)) is now available for prescribing under the National Blood Arrangements and will be available for supply from 1 May 2023.

The approved access conditions for intravenous immunoglobulin (IVIg) under the National Blood Arrangements are outlined on the National Blood Authority website at:

https://www.blood.gov.au/Intravenous-Ig

INDICATION

KIOVIG administered intravenously is registered for use in:

1. Replacement therapy indications

- Primary immunodeficiency disorders (PID);
- Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.

2. Immunomodulation indications

- Idiopathic thrombocytopenia purpura (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count;
- Guillain Barré Syndrome;
- Kawasaki Disease;
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) in adults;
- Multifocal Motor Neuropathy (MMN)

PACK SIZES AND ADMINISTRATION

KIOVIG is available in the following pack sizes:

- 1.0g in a 10mL solution
- 2.5g in a 25mL solution
- 5.0g in a 50mL solution
- 10g in a 100mL solution
- 20g in a 200mL solution
- 30g in a 300mL solution

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The dose and dosage regimen are dependent on the Indication and body weight.

Please click here https://www.takeda.com/en-au/what-we-do/ourproducts/ to access the KIOVIG Product Information for more information about dosage and administration.

ADDITIONAL INFORMATION

For additional information, please contact Takeda Medical Information via phone on 1800 012 612 or email: medinfoAPAC@takeda.com. Adverse events related to KIOVIG® (Normal immunoglobulin (Human)) should be reported by healthcare professionals to the Takeda Australia Pharmacovigilance department on 1800 012 612 or by email to AE.ANZ@takeda.com. Alternatively, this information can be reported to the TGA.

Please review Product Information before prescribing.

PBS Information: This Product is not listed on the PBS. Please refer to the National Blood Authority for details.

Takeda Pharmaceuticals Pty Ltd, Sydney, NSW 2000. Tel: 1800 012 612.

Email: medinfoAPAC@takeda.com. ABN 71 095 610 870. Date of Preparation: February 2023; C-APROM/AU/KIO/0004

Minimum Product Information for KIOVIG® (normal immunoglobulin infusion 10% (human))

Please review Product Information before prescribing. Product Information is available from Takeda Pharmaceuticals Australia Pty Ltd. Phone: 1800 012 612. Email: medinfoAPAC@takeda.com

Indications: KIOVIG administered **intravenously (IV)** is indicated for replacement therapy in primary immunodeficiency disorders (PID), symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment; immunomodulation therapy in idiopathic thrombocytopenia purpura (ITP) in patients at high risk of bleeding or prior to surgery to correct the platelet count**,** Guillain Barré Syndrome (GBS), Kawasaki disease, Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), and Multifocal Motor Neuropathy (MMN). KIOVIG administered **subcutaneously (SC)** is indicated for replacement therapy in Primary Immunodeficiency Disease (PID) only. **Contraindications:** known anaphylactic or severe hypersensitivity responses to Immunoglobulin (human). Patients with severe selective Immunoglobulin A (IgA) deficiency (IgA<0.05g/L) may develop anti-IgA antibodies that can result in a severe anaphylactic reaction. Such patients should only receive intravenous immunoglobulin (IVIG) when it's clearly indicated, and be monitored with supportive care available for treating life-threatening reactions. **Precautions:** Thrombotic and thromboembolic events. Renal adverse reactions including renal dysfunction, acute renal failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death. Periodic monitoring of renal function tests and urine output in patients who have increased risk of acute renal failure. Haemolysis. Infusion-related reactions (e.g., headache, flushing, and changes in blood pressure). Slower rates of infusion considered for certain patients (e.g., patients with hypo- or agammaglobulinemia; patients who receive human normal IG for the first time, or their IG product is switched, or there has been a long interval since last infusion; patients at risk of acute renal failure or thromboembolic ADRs; patients who have underlying renal disease). Hyperproteinemia, increased serum viscosity and hyponatremia. Viral transmission. Hypersensitivity reactions including anaphylaxis. Aseptic meningitis syndrome. IgA deficiency. Noncardiogenic pulmonary oedema. Paediatric use. Limited information is available for the use in the elderly. Misleading positive results in serological testing, false positive readings in assays that depend on detection of beta-D-glucans for diagnosis of fungal infections. Pregnancy category (B2). **Interactions:** Antibodies in IVIG products may interfere with patient responses to live vaccines such as measles, rubella, mumps and varicella. KIOVIG should not be mixed with IG products from other manufacturers. **Adverse effects:** *Very Common:* Headache, hypertension, nausea, rash, local reactions, fatigue, pyrexia, cough, vomiting, diarrhoea, pain in extremity, oropharyngeal pain, muscular weakness, back pain, influenza-like illness. *Common:* Anaemia, anxiety, irritability, insomnia, dizziness, migraine, paraesthesia, conjunctivitis, tachycardia, flushing, nasal congestion, rhinorrhoea, dyspnoea, dyspepsia, abdominal pain, contusion, urticaria, pruritus, dermatitis, erythema, arthralgia, muscle spasms, myalgia, infusion site extravasation, infusion site pain, infusion site swelling, chills, oedema, malaise, chest discomfort/tightness, lymphadenopathy, anaemia, vertigo, pharyngolaryngeal pain, white blood cell count decreased, blood

creatinine increased, blood urea increased, alanine aminotransferase increased, phlebitis, balance disorder, pulmonary embolism, photosensitivity reaction, night sweats, muscle twitching, proteinuria. **Dosage and Administration:** *IV administration*: dose and dosage regimen are dependent on the indication; in replacement therapy dosage may be individualised depending on the pharmacokinetic and clinical response. The following dosing regimens are given as a guideline: *PID*: recommended starting dose is 0.4-0.8 g/kg, thereafter 0.2-0.8 g/kg every 2-4 weeks. *Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment*: 0.2-0.4 g/kg every 3-4 weeks. *ITP*: 0.8-1 g/kg on day 1, possibly repeated once within 3 days, or 0.4 g/kg for 2-5 days. *GBS*: 0.4 g/kg for 3-7 days. *Kawasaki disease*: 1.6-2 g/kg in several doses in association with acetylsalicylic acid, or 2 g/kg in one dose in association with acetylsalicylic acid. *CIDP*: starting dose 2 g/kg in divided doses over 2-5 days; maintenance dose 1 g/kg over 1-2 consecutive days over 3 weeks. *MMN*: starting dose 2 g/kg in divided dose over 2-5 days; maintenance dose 0.4-2 g/kg every 2-6 weeks. *SC administration:* see full Product Information for guidance on dosing and administration.

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