

Guide to switching patients to *Kiovig 10%* (100 mg/ml) IVIg therapy



KIOVIG 10% WILL BE FUNDED AND SUPPLIED UNDER THE NATIONAL BLOOD ARRANGEMENTS ONLY AS AN IVIG PRODUCT AT THIS TIME.

→ General remarks:

- Consult the Product Information before use¹
- *Kiovig 10%* does not need to be reconstituted
- As a precautionary measure, a patient switched to *Kiovig 10%* should be infused at a speed that is lower than she/he was used to with the previous brand. The guidance provided in the PI should be followed (refer to section *DOSAGE AND ADMINISTRATION: For Intravenous (IV) Administration—Rate of Administration* in the PI)
 - Certain reactions may occur more frequently, in rare cases, in patients who receive human normal immunoglobulin for the first time, or when the human normal immunoglobulin product is switched or when there has been a long interval since the previous infusion. Patients should be monitored during the first infusion and for the first hour after the first infusion, in order to detect potential adverse signs
 - In most cases, the incidence of adverse events* will be reduced after 3–6 months²
- Assess the patient for pre-existing or recently developed risk factors for adverse events, in particular thrombo-embolic events
- For more information refer to sections *CONTRAINDICATIONS; PRECAUTIONS; INTERACTIONS WITH OTHER MEDICINES;* and *ADVERSE EFFECTS*

→ Before the infusion:

Refer to section *DOSAGE AND ADMINISTRATION: For Intravenous (IV) Administration—Recommended Dose and Dosage Adjustment*

- *Kiovig 10%* should be at room temperature during administration
- Even if the previous IMg was a 5% (50mg/ml) or 6% (60mg/ml) product, *Kiovig 10%* does not require dilution (*Kiovig 10%* is approximately iso-osmolar with human plasma as stated in the Certificate of Analysis). If, however, dilution is warranted, 5% glucose in water may be used as a diluent (e.g. if dilution to a 5% solution is desired, *Kiovig 10%* should be diluted with an equal volume of 5% glucose). Refer to section *DOSAGE AND ADMINISTRATION: For Intravenous (IV) Administration—Rate of Administration*.
- The patient should be adequately hydrated, or offered something to drink, in order to reduce the risk of hyperviscosity (refer to section *PRECAUTIONS*).

→ At the beginning/during the infusion:

Refer to sections *DOSAGE AND ADMINISTRATION: For Intravenous (IV) Administration and PRECAUTIONS*

- It is recommended that *Kiovig 10%* be infused intravenously at an initial rate of 0.5ml/kg/hr for 30 minutes (refer to section *DOSAGE AND ADMINISTRATION: For Intravenous (IV) Administration—Rate of Administration*)
- In patients with special sensitivity, or risk factors initially infuse at an even lower rate (refer to section *DOSAGE AND ADMINISTRATION: For Intravenous (IV) Administration—Rate of Administration and PRECAUTIONS*)
- The patient should be closely monitored and carefully observed for any symptoms throughout the infusion period
- The dose and dosage regimen are dependent on the indication
- Tolerability and patient comfort are individually different
- The infusion rate should be gradually increased, depending on patient comfort
- If well tolerated, the rate of administration may be gradually increased as tolerated up to a maximum of 5ml/kg BW/hr (refer to section *DOSAGE AND ADMINISTRATION: For Intravenous (IV) Administration—Rate of Administration*).
- In general, it is recommended that patients beginning treatment with IMg or switching from another IMg brand be started at the lowest rate and then increased to the maximal rate if they have tolerated several infusions at intermediate rates of infusion (refer to section *DOSAGE AND ADMINISTRATION: For Intravenous (IV) Administration—Rate of Administration*)
- If the patient reports an adverse event, the infusion rate should either be reduced or the infusion should be stopped
- Certain adverse reactions may occur more frequently, in rare cases, when the human normal immunoglobulin product is switched (refer to sections *PRECAUTIONS; INTERACTIONS WITH OTHER MEDICINES;* and *ADVERSE EFFECTS*)

→ After the first infusion:

- *Kiovig 10%* was reported to be well tolerable in the three pivotal clinical studies, conducted in the EU and the US³⁻⁵

*Adverse Event (AE): Any untoward medical occurrence in a subject administered a medicinal product. The term does not necessarily imply a causal relationship with the medicinal product

Suspected Adverse Drug Reaction (SADR): The adverse event is suspected to be product related



Patient details

Date	Dose	Maximum Rate	Comments

40kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	8	12	16	20	24	32	40	80
Volume (mL)	80	120	160	200	240	320	400	800
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 20 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	20	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	40	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	80	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	120	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	160	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	200	0:21	0:33	0:45	0:57	1:09	1:33	1:57

45kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	9	13.5	18	22.5	27	36	45	90
Volume (mL)	90	135	180	225	270	360	450	900
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 22.5 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	22.5	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	45	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	90	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	135	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	180	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	225	0:21	0:33	0:45	0:57	1:09	1:33	1:57

50kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	10	15	20	25	30	40	50	100
Volume (mL)	100	150	200	250	300	400	500	1000
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 25 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	25	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	50	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	100	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	150	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	200	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	250	0:21	0:33	0:45	0:57	1:09	1:33	1:57

55kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	11	16.5	22	27.5	33	44	55	110
Volume (mL)	110	165	220	275	330	440	550	1100
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 27.5 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	27.5	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	55	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	110	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	165	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	220	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	275	0:21	0:33	0:45	0:57	1:09	1:33	1:57

60kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	12	18	24	30	36	48	60	120
Volume (mL)	120	180	240	300	360	480	600	1200
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 30 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	30	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	60	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	120	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	180	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	240	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	300	0:21	0:33	0:45	0:57	1:09	1:33	1:57

65kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	13	19.5	26	32.5	39	52	65	130
Volume (mL)	130	195	260	325	390	520	650	1300
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 32.5 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	32.5	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	65	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	130	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	195	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	260	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	325	0:21	0:33	0:45	0:57	1:09	1:33	1:57

70kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	14	21	28	35	42	56	70	140
Volume (mL)	140	210	280	350	420	560	700	1400
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 35 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	35	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	70	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	140	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	210	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	280	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	350	0:21	0:33	0:45	0:57	1:09	1:33	1:57

80kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	16	24	32	40	48	64	80	160
Volume (mL)	160	240	320	400	480	640	800	1600
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 40 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	40	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	80	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	160	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	240	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	320	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	400	0:21	0:33	0:45	0:57	1:09	1:33	1:57

90kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	18	27	36	45	54	72	90	180
Volume (mL)	180	270	360	450	540	720	900	1800
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 45 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	45	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	90	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	180	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	270	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	360	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	450	0:21	0:33	0:45	0:57	1:09	1:33	1:57

100kg

DOSAGE (g/kg)	0.2	0.3	0.4	0.5	0.6	0.8	1	2
Dose (g)	20	30	40	50	60	80	100	200
Volume (mL)	200	300	400	500	600	800	1000	2000
During the first 30 minutes of infusion, initial flow rate is 0.5 mL/kg/h or 50 mL/h*								
After the first 30 minutes, select the speed and read the infusion time (h:min)								
Rate		Infusion time (h:min)						
mL/kg/h	mL/h	3:30	5:30	7:30	9:30	11:30	15:30	19:30
0.5	50	3:30	5:30	7:30	9:30	11:30	15:30	19:30
1	100	1:45	2:45	3:45	4:45	5:45	7:45	9:45
2	200	0:52	1:22	1:52	2:22	2:52	3:52	4:52
3	300	0:35	0:55	1:15	1:35	1:55	2:35	3:15
4	400	0:26	0:41	0:56	1:11	1:26	1:56	2:26
5	500	0:21	0:33	0:45	0:57	1:09	1:33	1:57

Please review full product information before prescribing. Product information is available from Baxter Medical Information 1300 302 409 or onecall@baxter.com

MINIMUM PRODUCT INFORMATION *Name of the drug:* KIOVIG *Chemical Name:* Normal Immunoglobulin (human) **Indications** KIOVIG, IVIG 10% Solution is indicated for the treatment of: 1. primary immunodeficiency disorders (PID) associated with defects in humoral immunity, acting as a replacement therapy, 2. secondary immunodeficiency syndromes, 3. immunomodulation. **Contra-indications:** KIOVIG, IGIV 10% Solution is contraindicated in patients with known anaphylactic or severe hypersensitivity responses to Immune Globulin (human). Patients with severe selective IgA deficiency (IgA < 0.05g/L) may develop anti-IgA antibodies that can result in a severe anaphylactic reaction. **Precautions** *Viral transmission:* This product is manufactured using components of human blood, which may contain the causative agents of hepatitis and other viral diseases, and theoretically Creutzfeldt-Jacob Disease (CJD) agents. Prescribed manufacturing procedures utilised at the plasma collection centres and plasma-testing laboratories are designed to reduce the risk of transmitting viral infection. **Allergic reaction:** As with any intravenous product, in particular with a protein substance, allergic type hypersensitivity reactions are possible. **Serious Warning:** Immune Globulin Intravenous (human) products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Patients predisposed to acute renal failure include patients with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65 years, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Especially in such patients, IGIV products should be administered at the minimum concentration available and the minimum rate of infusion practicable. While these reports of renal dysfunction and acute renal failure have been associated with the use of many of the licensed IGIV products, those containing sucrose as a stabiliser accounted for a disproportionate share of the total number. Formulation of KIOVIG, IGIV 10% Solution used Glycine, an amino acid as a stabiliser and it does not contain sucrose. The physician should discuss the risks and benefits of this product with the patient. **Adverse Reactions** Adverse reactions such as chills, headache, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain may occur occasionally. Rarely human normal immunoglobulins may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration. **Dosage and Administration** The dose and dosage regimen are dependent on the indication. In replacement therapy the dosage may need to be individualised for each patient depending on the pharmacokinetic and clinical response. **Recommended Dose and Dosage Adjustment:** KIOVIG is intended for intravenous and subcutaneous administration. Dosage will vary depending on condition and bodyweight. KIOVIG should be at room temperature during administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use if particulate matter and/or discoloration is observed. Only clear or slightly opalescent and colourless or pale yellow solutions are to be administered. The use of an in-line filter is optional. **For Subcutaneous (SC) Administration** If self-administration at home or other appropriate setting is planned, the healthcare professional should provide the patient or the carer with adequate training in terms of the correct technique of subcutaneous administration and the correct recognition and management in cases of acute adverse reactions. For detailed instructions, please refer to the Instruction Leaflet for subcutaneous administration in the package insert. **SC Dosage:** Prior to switching from intravenous to subcutaneous treatment, obtain the patient's serum IgG trough level to guide subsequent dose adjustments. Start the initial subcutaneous dose approximately one week after the last intravenous infusion in a patient who has been on stable intravenous therapy. Convert the IV dose into weekly equivalents and recheck a serum IgG after several months. The level should be the same or higher than when treated intravenously. Because there is a wide variation in metabolism of IgG between patients with immune deficiency diseases, it is important to individualise dosing. The most important factor when determining dosage of IgG is the clinical response of the patient. **SC Administration:** Use of an infusion pump and multi-needle administration set is recommended. **Selection of Infusion Site:** Suggested areas for subcutaneous infusion of KIOVIG are abdomen, thighs, upper arms, or lower back. Infusion sites should be at least two inches apart, avoiding bony prominences. Rotate sites each week. **Volume per Site:** The recommended maximum volume is 30 mL/site for patients above 40 kg (88 lbs) and 20 mL/site for patients under 40 kg (88 lbs). The weekly dose (mL) should be divided by 30 or 20, based on patient weight above, to determine the number of sites required. Simultaneous subcutaneous infusion at multiple sites can be facilitated by use of a multi-needle administration set. **Rate of Infusion:** Patients over 40 kg (88 lbs): For the first infusion, the recommended maximum rate of infusion of KIOVIG is 20mL/hr/site. For subsequent infusions, the flow rate should be adjusted as tolerated to a maximum of 30 mL/hr/site. If multiple sites are used, the rate set on the pump should be the rate per site multiplied by the number of sites (e.g., 30 mL x 4 sites = 120 mL/hr). The number of simultaneous sites should be limited to 8, or maximum infusion rate of 240 mL/hr. **Patients under 40 kg (88 lbs):** For the first infusion, the recommended maximum rate of infusion of KIOVIG is 15mL/hr/site. For subsequent infusions, the flow rate should be adjusted as tolerated to a maximum of 20 mL/hr/site. If multiple sites are used, the rate set on the pump should be the rate per site multiplied by the number of sites (e.g., 20 mL x 3 sites = 60 mL/hr). The number of simultaneous sites should be limited to 8, or maximum infusion rate of 160 mL/hr. **Name and address of the sponsor:** KIOVIG is manufactured by: Baxter AG, Industriestasse 67, A-1221, Vienna, Austria. **Distributed in Australia by:** Baxter Healthcare Pty Ltd, 1 Baxter Drive, Old Toongabbie, NSW 2146 **Approved by the TGA:** 30 November 2011

PBS Information: This product is not listed on the PBS. KIOVIG is funded by the National Blood Authority. Please refer to the National Blood Authority for details.

References:

1. *Kiovig 10%* Australian Product Information, 30 November 2011.
2. Final study report, Data on file, Baxter Healthcare Corporation.
3. Björkander J, Nikoskelainen J, Leibl H, Lanbeck P, Wallvik J, Lu.mio JT, Braconier JH, Pavlova BG, Birstistle K, Engl W, Walter S & Ehrlich HJ. *Prospective open label study of pharmacokinetics, efficacy and safety of a new 10% liquid intravenous immunoglobulin in patients with hypo- or agammaglobulinemia.* Vox Sang 2006, 90: 286 - 293.
4. Church JA, Leibl H, Stein MR, Melamed IR, Bubinstein A, Schneider LC, Wasserman RL, Pavlova BG, Birstistle K, Mancini M, Fritsch S, Partone L, Moore-Perry K, Ehrlich HJ & US-PID-IGIV 10% Study Group. *Efficacy, Safety and Tolerability of a New 10% Liquid Intravenous Immune Globulin (IGIV 10%) in Patients with Primary Immunodeficiency.* J. of Clinical Immunology 2006, 26 (4): 388 - 395.
5. Varga G, Volkova Z, Leibl H, Gasztonyi Z, Hlusi A, Mayer J, Chojnowski K, Wolf HH, Sharkhaw M, Pavlova BG, Birstistle K, Engl W, Walter S, Ehrlich HJ & ITP-IGIV 10% Study Group. *Efficacy and Safety of a New Intravenous Immunoglobulin IGIV 10% in Adults with Chronic Idiopathic Thrombocytopenic Purpura.* Transfusion Medicine and Hemotherapy 2006, 33 (6): 509 - 514.

Kiovig 10% will be funded and supplied under the national blood arrangements only as an IVIG product at this time.

Baxter

AUSTRALIA

Baxter Healthcare Pty Ltd
1 Baxter Drive, Old Toongabbie
NSW 2146 Australia
Tel: +61 2 9848 1111
Fax: +61 2 9848 1123
www.baxterhealthcare.com.au

NEW ZEALAND

Baxter Healthcare Ltd
33 Vestey Drive, Mount Wellington
Auckland 1006, New Zealand
Tel: +64 9 574 2400
Fax: + 64 (0) 800 229 329
www.baxter.co.nz

Medical Information:

1300 302 409 or email onecall@baxter.com
PA042B/2011