

## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### **1. Why am I treated with KIOVIG?**

KIOVIG contains the active ingredient normal immunoglobulin (human). KIOVIG is used for the treatment of patients who do not have sufficient antibodies (replacement therapy). KIOVIG is also used for the treatment of patients with certain inflammatory disorders (immunomodulation).

For more information, see Section [1. Why am I treated with KIOVIG?](#) in the full CMI.

### **2. What should I know before treatment with KIOVIG?**

Do not use if you have ever had an allergic reaction to immunoglobulins or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before treatment with KIOVIG?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with KIOVIG and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How is KIOVIG given?**

- KIOVIG is a 10% solution (100 mg/mL) for intravenous or a subcutaneous infusion.

More instructions can be found in Section [4. How is KIOVIG given?](#) in the full CMI.

### **5. What should I know during treatment with KIOVIG?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are being treated with KIOVIG</li></ul>
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	<ul style="list-style-type: none"> <li>• Tell your doctor, if you are suffering from an immunoglobulin A deficiency or planning to receive an immunization</li> <li>• Discuss with your doctor, the progress you have experienced following the treatment.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not attempt to self-administer unless you have been trained by your healthcare professional</li> <li>• Use of KIOVIG during pregnancy or breast-feeding is not recommended.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store at 2°C to 8°C for up to 36 months. Refrigerate. Do not freeze.</li> <li>• Keep the container in the outer carton to protect from light.</li> </ul>

For more information, see Section [5. What should I know during treatment with KIOVIG?](#) in the full CMI.

## 6. Are there any side effects?

Infusion site side reactions include, redness, warmth, itching, swelling, mild or moderate pain and bruising. Side effects that may occur during infusion include, headache, migraine, chills, mild fever, fatigue, weakness, nausea, rash/hives, increased heart rate, abdominal pain, dizziness /increased blood pressure. Serious side effects: fever or other signs of an infection, chest pain or breathing problems, night sweats, reduced urination, sudden weight gain, or swelling in your legs, brown or red urine, fast heart rate, yellow skin, or eyes. Very serious side effects: hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness; bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light; pain, swelling, warmth, redness, or a lump in your legs or arms; chest pain or trouble breathing, blue lips or extremities.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# KIOVIG®

**Active ingredient(s):** *normal immunoglobulin (human)*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about treatment with KIOVIG. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KIOVIG.**

**Where to find information in this leaflet:**

- [1. Why am I treated with KIOVIG?](#)
- [2. What should I know before treatment with KIOVIG?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is KIOVIG given?](#)
- [5. What should I know during treatment with KIOVIG?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I treated with KIOVIG?

**KIOVIG contains the active ingredient human plasma derived immunoglobulin (IgG) protein.**

KIOVIG belongs to a class of medicines called immunoglobulins. These medicines contain human antibodies, which are also present in your blood. Antibodies help your body to fight infections.

Immunoglobulins are used in patients who do not have enough antibodies in their blood and tend to get frequent infections. They can also be used in patients who need additional antibodies for the treatment of certain inflammatory disorders.

The active component in KIOVIG, immunoglobulin, is isolated from the plasma of human donors. As required by the Regulatory Authority, the viral DNA testing procedures for finding out whether the collected bloods contain infectious viruses have been incorporated in the process. Possible viruses which may be present in the donated blood include hepatitis (A, B and C), human immunodeficiency virus (HIV), and parvovirus B19.

Further viral inactivation procedure has also been included during the manufacturing steps to reduce a potential viral transmission via KIOVIG administration. A three-step viral inactivation/reduction has been applied during the manufacturing of KIOVIG. Despite the stringent measures, which have been put in place during the manufacturing processes, the risk of contamination by viral and other unknown agents cannot be completely eliminated.

### **KIOVIG is used for:**

#### **Treatment of patients who do not have sufficient antibodies (replacement therapy):**

- Primary immunodeficiency disorders
- Disease or medical treatment that leads to a lack of antibody production and frequent infection (secondary hypogammaglobulinemia).

## **Treatment of patients with certain inflammatory disorders (immunomodulation):**

- Idiopathic thrombocytopenic purpura (ITP, a disease where patients do not have enough blood platelets), who are at high risk of bleeding or prior to surgery to correct the platelet count.
- Guillain Barré syndrome (a disease with multiple inflammations of the nervous system of the whole body)
- Kawasaki disease (a disease which results in multiple inflammations of several organs)
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) in adults
- Multifocal motor neuropathy (a rare condition characterised by slow progressive asymmetrical weakness of limbs without sensory loss).

## **2. What should I know before treatment with KIOVIG?**

### **Warnings**

#### **Do not use KIOVIG if:**

- you are hypersensitive (allergic) to immunoglobulin, or any of the ingredients listed at the end of this leaflet
- always check the ingredients to make sure you can use this medicine
- you are suffering from an immunoglobulin A deficiency (lack of IgA antibodies), you may have antibodies

against immunoglobulin A in your blood. Since KIOVIG contains small amounts of immunoglobulin A, you might develop an allergic reaction.

### **Check with your doctor if you:**

- are suffering from an immunoglobulin A deficiency
- have or have had any kidney problem
- have or have ever had cerebrovascular disease (such as a stroke) or cardiovascular disease (such as a heart attack or angina), including high blood pressure and narrowing or hardening of the arteries
- have any heart condition or problem
- are a smoker
- have previously had a blood clot in your legs (deep vein thrombosis), lungs (pulmonary embolism) or other parts of your body
- have immediate family members who have had blood clots in the legs, a heart attack, a stroke, or high cholesterol
- diabetes
- have any other medical conditions
- are taking the contraceptive pill or hormone replacement treatment
- are having difficulty in breathing or fatigue (anaemic).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The use of KIOVIG during pregnancy or breast-feeding is not recommended, due to insufficient information in supporting of such usages. If there is a need to consider the use of this product during pregnancy, it should only be given in such condition if clearly needed. Ask your doctor about the risks and benefits involved.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any prescription medicine or any other medicines purchased from a pharmacy, health food store or supermarket. Some medicines and KIOVIG may interfere with each other.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KIOVIG treatment.**

## 4. How is KIOVIG given?

### How much is given

- KIOVIG is a 10% solution (100 mg/mL) of human immunoglobulin (IgG) for intravenous or subcutaneous infusion
- Your doctor will decide how much KIOVIG will be given to you. Dosage will vary depending on your condition and your bodyweight. Each individual will receive a different dosage, which in itself may vary between doctor visits
- Ask your doctor if you want to know more about the dose of KIOVIG you receive
- Follow the instructions provided and use KIOVIG until your doctor tells you to stop.

### How is KIOVIG given

- KIOVIG is given as an intravenous (into a vein) or a subcutaneous (under the skin) infusion. Your doctor will decide which way is best for you.
- At the beginning of your infusion, you will receive KIOVIG at a slow rate. Depending on how comfortable you are, your doctor may then gradually increase the infusion rate.
- When given subcutaneously, the dose may be infused through several needles simultaneously. Do not exceed the recommended maximum amount given through each needle.

- If your doctor decides that you may administer KIOVIG yourself, your doctor or nurse will teach you how to prepare and give the infusion subcutaneously (under the skin).
- Do not attempt to administer KIOVIG yourself until you have been trained and understand the procedure and requirement of self-administration.
- There is an Instruction Leaflet for subcutaneous administration inside the box which describes the procedures involved.
- Ask your doctor any questions you may have about KIOVIG.

## **If you use too much KIOVIG**

If you think that you have used too much KIOVIG, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know during treatment with KIOVIG?**

### **Things you should do**

Discuss with your doctor the progress you have experienced after the treatment, especially during the first few days. As KIOVIG is generally given in a hospital, your healthcare professional will take records of the progress and unexpected reactions.

**You must tell your doctor if you are planning to receive an immunization.**

Immunoglobulins may impair the effects of some virus vaccines such as mumps, rubella, and varicella for up to 6 months and for a year or more to measles (rubeola). Inform the immunising physician of recent therapy with KIOVIG so that appropriate precautions can be taken.

Remind any doctor, dentist, or pharmacist or any other health professionals you visit that you are using KIOVIG.

### **Driving or using machines**

No information available. Be careful before you drive or use any machines or tools until you know how KIOVIG affects you.

### **Drinking alcohol**

No information available.

## Looking after your medicine

- Store at 2°C to 8°C
- Refrigerate. Do not freeze.
- Do not use this medicine after the expiry date.

Keep the container in the outer carton to protect from light.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. Certain side effects, e.g., headache or flushing, may be reduced by slowing the infusion rate. However, some side effects may need medical attention.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are under KIOVIG treatment.**

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>At the site of infusion:</b></p> <ul style="list-style-type: none"><li>• redness</li><li>• warmth</li><li>• itching</li><li>• swelling</li><li>• mild or moderate pain</li><li>• bruising</li></ul> <p><b>During infusion:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• migraine</li><li>• chills</li><li>• mild fever</li><li>• fatigue</li><li>• weakness</li><li>• nausea</li><li>• rash/hives</li><li>• increased heart rate</li><li>• abdominal pain</li><li>• dizziness /increased blood pressure</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p>These generally go away within a few hours and are less likely after the first few infusions.</p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>● Fever or other signs of an infection</li> <li>● Chest pain or breathing problems</li> <li>● Night sweats</li> <li>● Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.</li> <li>● Brown or red urine, fast heart rate, yellow skin, or eyes. These could be signs of a liver problem or a blood problem.</li> </ul>	<p><b>Tell your doctor as soon as possible if you notice any of these side effects</b></p> <p>This list includes serious side effects that may require medical attention.</p>
<ul style="list-style-type: none"> <li>● Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.</li> <li>● Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light.</li> </ul>	<p><b>Tell your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>These could be signs of irritation of the lining around your brain.</p> <ul style="list-style-type: none"> <li>● Pain, swelling, warmth, redness, or a lump in your legs or arms. These could be signs of a blood clot.</li> <li>● Chest pain or trouble breathing, blue lips or extremities. These could be signs of a serious heart or lung problem.</li> </ul>	<p>This list includes very serious side effects. You may need urgent medical attention or hospitalisation.</p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What KIOVIG contains**

<b>Active ingredient</b>	Human plasma derived immunoglobulin (IgG) protein.
<b>Other ingredients</b>	Glycine, water for injections
<b>Potential allergens</b>	KIOVIG contains a small amount of immunoglobulin A.

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What KIOVIG looks like**

KIOVIG is a clear or slightly opalescent and colourless or pale-yellow solution.

**Do not use this medicine, if you notice particulate matter or discolouration of the solution.**

KIOVIG is available in single use glass vials of:

1 g in 10 mL - AUST R 131953

2.5 g in 25 mL - AUST R 131966

5 g in 50 mL - AUST R 131968

10 g in 100 mL - AUST R 131969

20 g in 200 mL - AUST R 131973

30 g in 300 mL - AUST R 198488

*Not all pack sizes may be distributed.*

## **Who distributes KIOVIG?**

KIOVIG is distributed in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street,

Sydney NSW 2000

Australia

Phone: 1800 012 612

This leaflet was prepared in May 2022.

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