KIOVIG

What is in this leaflet?

This leaflet answers some common questions about the KIOVIG. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks against the benefits for you by using KIOVIG.
It does not take the place of talking to your doctor or pharmacist. If you have any concerns about having this medicine, ask your doctor or pharmacist. Please read this leaflet carefully and keep it for future reference. Please also note that this leaflet is subjected to change, therefore, ask your doctor whether this is the latest information regarding this medicine.

What KIOVIG is used for

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 hypogammaglobulinaemia).

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)

How does KIOVIG work

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 in order 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.

Before you are given KIOVIG

KIOVIG should not be given to you:

- If you are hypersensitive (allergic) to immunoglobulin or to any of the ingredients listed at the end of this leaflet
    - If 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.
- The expiry date printed on the pack has past.

You must tell 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 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.

You must tell your doctor, if you are pregnant, planning to become pregnant or breast-feeding.
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.

How KIOVIG is given

- ***How much is given:***

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.

- ***How is it 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.

While you are treated with KIOVIG

Discuss with your doctor the progress you have experienced after the treatment, especially during the first few days. As KIOVIG is 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.

Possible Adverse Effects Using this Medicine

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are under KIOVIG treatment.
All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- The following reactions may occur at the site of infusion. These generally go away within a few hours, and are less likely after the first few infusions.
    - redness
    - warmth
    - itching
    - swelling
    - mild or moderate pain
    - bruising

- the following common side effects may occur during infusion of KIOVIG:
    - headache
    - migraine
    - chills
    - mild fever
    - fatigue
    - nausea
    - rash/hives
    - increased heart rate
    - abdominal pain
    - dizziness /increased blood pressure

Tell your doctor as soon as possible if you notice any of the following:

- Fever or other signs of an infection
- Chest pain or breathing problems
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.

- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver problem or a blood problem.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation of the lining around your brain.
- Pain, swelling, warmth, redness, or a lump in your legs or arms. These could be signs of a blood clot.
- Chest pain or trouble breathing, blue lips or extremities. These could be signs of a serious heart or lung problem.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

Product descriptions

What KIOVIG looks like

KIOVIG is a 10% solution (100 mg/mL) for intravenous/subcutaneous infusion. The solution is clear or slightly opalescent and colourless or pale yellow.

KIOVIG is available in single use glass vials of:

- 1 g in 10 mL
- 2.5 g in 25 mL
- 5 g in 50 mL
- 10 g in 100 mL
- 20 g in 200 mL.

What is in KIOVIG

The active component/ingredient in KIOVIG is human plasma derived Immunoglobulin (IgG) protein. Other ingredients in KIOVIG include:

- Glycine, a natural amino acid
- Water for Injections.

(It also contains a small amount of immunoglobulin A.)

How to store KIOVIG

Keep out of the reach and sight of children.
Keep the container in the outer carton in order to protect from light.

Refrigeration storage: Store at 2°C – 8°C (Refrigerate. Do not Freeze).

Do not use after the expiry date stated on the label.

Where can you get more information

You can get more information from your doctor or pharmacist. KIOVIG is a prescription drug. If you require further information regarding KIOVIG, or your treatment, or if you have any questions or are not sure about the information provided in this leaflet, please consult your doctor.

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 2148

Australian Registration Number

KIOVIG (Normal Immunoglobulin):

- 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

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