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Kiovig (*human normal immunoglobulin*)

An overview of Kiovig and why it is authorised in the EU

What is Kiovig and what is it used for?

Kiovig is a medicine used to support the immune system (the body's natural defences) in two main groups of patients:

- Patients at risk of infection because they do not have enough antibodies (also called immunoglobulins, proteins in the blood that help the body to fight disease). These can be people who are born with a lack of antibodies (primary immunodeficiency syndrome, PID). These also include people who have developed a lack of antibodies after birth (secondary immunodeficiency syndrome, SID), who have low levels of certain antibodies (called IgG) and who suffer from infections that are severe, keep coming back, and are not cured by medicines used to treat infections;
- Patients with certain immune disorders. These comprise patients with primary immune thrombocytopenia (ITP), who do not have enough platelets (components in the blood that help it to clot) and who are at high risk of bleeding; patients with Guillain-Barré syndrome or chronic inflammatory demyelinating polyneuropathy (CIDP), inflammatory disorders of the nerves that result in muscle weakness and numbness; patients with Kawasaki disease, a disease mainly seen in children which causes inflammation of blood vessels; and patients with multifocal motor neuropathy (MMN), nerve damage which causes weakness of the arms and legs.

The medicine contains the active substance human normal immunoglobulin.

How is Kiovig used?

Kiovig can only be obtained with a prescription and treatment for patients with a lack of antibodies should be started and monitored by a doctor experienced in treating such conditions.

The medicine is given by infusion (drip) into a vein. The dose and frequency of infusions depend on the disease being treated and how well the disease is being controlled.

For more information about using Kiovig, see the package leaflet or contact your doctor or pharmacist.

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How does Kiovig work?

The active substance in Kiovig, human normal immunoglobulin, is a highly purified protein extracted from human plasma (part of the blood). It contains immunoglobulin G (IgG), which is a type of antibody. IgG has been used as a medicine since the 1980s and has a wide range of activity against organisms that can cause infection. Kiovig works by restoring abnormally low IgG levels to their normal range in the blood. At higher doses, it can help to adjust an abnormal immune system and modulate the immune response.

What benefits of Kiovig have been shown in studies?

As human normal immunoglobulin has been used to treat these diseases for a long time, and in accordance with current guidelines, 4 small studies were needed to establish the effectiveness and safety of Kiovig in patients.

In the first study, Kiovig was used to replace antibodies in 22 patients with PID who had very low or no levels of immunoglobulin. Kiovig was as effective as the standard treatment in preventing infections and reducing antibiotic use.

The second study looked at using Kiovig to adjust the immune system in 23 patients with ITP. Kiovig was shown to be effective in increasing the platelet count.

The third and fourth studies were in a total of 28 patients with MMN. Kiovig was effective in maintaining muscle strength and reducing disability.

What are the risks associated with Kiovig?

The most common side effects with Kiovig (seen in more than 1 patient in 10) are headache, hypertension (high blood pressure), nausea (feeling sick), rash, tiredness, local reactions such as pain, swelling or itching at the site of injection, and fever. Some side effects are more likely when using a high rate of infusion, in patients with low immunoglobulin levels, or in patients who have not received Kiovig before or for a long time.

Kiovig must not be used in people who are hypersensitive (allergic) to human normal immunoglobulin or any of the other ingredients, or in patients who are allergic to other types of human immunoglobulin, especially where they have very low levels of immunoglobulin A (IgA) and they have antibodies against IgA. For the full list of side effects and restrictions, see the package leaflet.

Why is Kiovig authorised in the EU?

Kiovig was shown to be effective in PID, ITP and MMN. Based on its effectiveness in these diseases, Kiovig can be approved for use in the treatment of other types of immunodeficiency, as well as low antibody levels due to Guillain-Barré syndrome, Kawasaki disease or CIPD, without the need for specific studies in these diseases. Therefore, the European Medicines Agency concluded that Kiovig's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Kiovig?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Kiovig have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Kiovig are continuously monitored. Side effects reported with Kiovig are carefully evaluated and any necessary action taken to protect patients.

Other information about Kiovig

Kiovig received a marketing authorisation valid throughout the EU on 19 January 2006.

Further information can be found on the Agency's website ema.europa.eu/medicines/EPAR/kiovig.

This overview was last updated in 03-2019.