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Privigen (*human normal immunoglobulin*)

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

What is Privigen and what is it used for?

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

- Patients who are 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 Privigen used?

Privigen 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 available as a solution for infusion (drip) into a vein.

The dose and frequency of infusions (how often it is given) depend on the disease being treated. The dose may need to be adjusted for patients depending on their response.

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

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How does Privigen work?

The active substance in Privigen, 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. Privigen 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 Privigen 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, only three small studies were needed to establish the effectiveness and safety of Privigen in patients. Privigen was not compared to other treatments in the studies.

In the first study, Privigen was used in 80 patients with PID, with the medicine being infused every three or four weeks. The main measure of effectiveness was the number of serious bacterial infections over a year's treatment. The patients had an average of 0.08 serious infections per year. Since this is below the predefined threshold of one serious infection per year, this indicates that the medicine is effective as replacement therapy.

The second study looked at using Privigen in 57 patients with ITP. Privigen was given on two consecutive days. The main measure of effectiveness was the highest blood platelet level that was achieved in the week after Privigen was given. In this study, 46 (81%) of the 57 patients had a platelet count above 50 million platelets per millilitre at least once during the study. This confirmed that Privigen is effective in immunomodulation.

A third study examined the use of Privigen for immunomodulation in 28 patients with CIDP who were given Privigen every three weeks over a period of 24 weeks. The main measure of effectiveness was the number of patients who showed improvement of their disability, measured by a decrease on a 10-point scale of disability in their arms and legs. In this third study, 17 (61%) of the 28 patients responded to treatment with an improvement of at least one point on the disability scale. The average improvement was about 1.4 points.

What are the risks associated with Privigen?

The most common side effects with Privigen (seen in more than 1 patient in 10) are headache, nausea, pain (including in the back, neck, limbs, joints and face), fever, chills and a flu-like illness.

Some side effects are more likely with a high rate of infusion, in patients with low immunoglobulin levels, or in patients who have not received human normal immunoglobulin before or for a long time. For the full list of all side effects with Privigen, see the package leaflet.

Privigen must not be used in people who are hypersensitive (allergic) to normal human immunoglobulin or any of the other ingredients, or in patients who are allergic to other types of immunoglobulins, especially where they have deficiency (very low levels) of immunoglobulin A (IgA) and they have antibodies against IgA. Privigen must not be used in patients with hyperprolinaemia type I or II (a genetic disorder causing high levels of the amino acid proline in the blood).

Why is Privigen authorised in the EU?

The European Medicines Agency concluded that Privigen'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 Privigen?

Haemolysis (breakdown of red blood cells) is an uncommon side effect in patients given human normal immunoglobulin (occurring with less than 1 dose in 100). Severe haemolysis has previously been reported to be slightly more frequent with Privigen than with some other products containing the same active substance. The company that markets Privigen has made some changes in the way it is produced to reduce this risk and is performing a study to monitor the effect of the changes.

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

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

Other information about Privigen

Privigen received a marketing authorisation valid throughout the EU on 25 April 2008.

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

This overview was last updated in 01-2019.