EMA/612651/2020
EMEA/H/C/000831

Privigen (*human normal immunoglobulin*)

A plain language 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 treat people who:

- are at risk of infection because they do not have enough antibodies, particularly immunoglobulin G (IgG). Antibodies are protein in the blood that helps the body fight infections. This includes:
  - people who are born with a lack of antibodies (primary immunodeficiency syndrome, PID);
  - people who develop a lack of antibodies after birth (secondary immunodeficiency syndrome, SID), who have low levels of IgG and suffer from infections that are severe or keep coming back despite treatment with medicines used to treat infections.
- have certain immune diseases caused by the body's own immune system attacking normal tissues. In these diseases, Privigen helps regulate the activity of the immune system (immunomodulation). These include:
  - primary immune thrombocytopenia (ITP), where people do not have enough platelets (components that help the blood to clot) and are at high risk of bleeding;
  - Guillain-Barré syndrome or chronic inflammatory demyelinating polyneuropathy (CIDP), inflammatory disorders of the nerves that cause muscle weakness and numbness;
  - Kawasaki disease, a disease mainly seen in children which causes inflammation of blood vessels;
  - multifocal motor neuropathy, a nerve disorder that causes weakness of the arms and legs.
- need protection against measles before or after exposure because they are at risk and cannot receive, or should not receive, measles vaccination.

The medicine contains the active substance human normal immunoglobulin.

How is Privigen used?

Privigen can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in treating people with immune system disorders.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The medicine is given by infusion (drip) into a vein. How often it is given depends on the disease being treated and the patient's bodyweight. For the treatment of Kawasaki disease, Privigen should be given together with aspirin (acetylsalicylic acid).

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

How does Privigen work?

Privigen contains the active substance human normal immunoglobulin, which consists of antibodies extracted and purified from the plasma (the liquid part of blood) of healthy people. In people with primary or secondary immunodeficiency, Privigen provides the IgG they lack, reducing their risk of infection. At higher doses, Privigen helps regulate the activity of the immune system in people with autoimmune disorders. In people susceptible to measles, Privigen provides antibodies against the measles virus that help prevent infection and its complications.

What benefits of Privigen have been shown in studies?

As human normal immunoglobulin has been used to treat people with immunodeficiency syndrome and immune disorders for a long time, three small studies were sufficient to establish the effectiveness and safety of Privigen. Privigen was not compared with placebo (a dummy treatment) or other treatments in these studies.

Primary immunodeficiency syndrome

In the first study, Privigen was used in 80 patients with PID, with the medicine being given every three or four weeks. The main measure of effectiveness was the number of serious bacterial infections that occurred over one year of treatment. 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 Privigen is effective as replacement therapy.

Immunomodulation

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

A third study evaluated Privigen in 28 patients with CIDP who were given Privigen every three weeks for 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 study, 61% of patients (17 out of 28) responded to treatment with an improvement of at least one point on the disability scale. The average improvement was about 1.4 points.

Prevention of measles disease

Antibodies against measles contained in human normal immunoglobulin medicines have long been known to prevent measles infection and reduce the risk of complications in people at risk of severe disease, particularly when given soon after exposure to the virus. This is supported by studies published in the medical literature on the use of these medicines.

Studies carried out with Privigen are described in more detail in the medicine's assessment reports.

What are the side effects and restrictions with Privigen?

For the full list of side effects and restrictions with Privigen, see the package leaflet.

The most common side effects with Privigen (which may affect more than 1 in 10 people) include headache, pain (including in the back, neck, arms and legs, joints and face), fever, chills and a flu-like illness.

Some side effects are more likely to occur 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.

Privigen must not be used in patients who have deficiency (very low levels) of immunoglobulin A (IgA) and who have antibodies against IgA. This is because it could cause a severe allergic reaction (anaphylaxis) in these patients. Privigen must also 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?

Privigen was shown to reduce the risk of infection in patients with PID and to improve symptoms of ITP and CIDP. Based on these results, Privigen is also expected to alleviate symptoms of Guillain-Barré syndrome, Kawasaki disease and multifocal motor neuropathy.

The use of human normal immunoglobulin medicines such as Privigen to help prevent measles in people at risk of severe disease is well established. Published studies have shown that these medicines can provide protection against measles. Privigen is therefore expected to be effective in preventing measles infection.

Medicines containing human normal immunoglobulin have been used in the EU since the 1980s. Privigen's side effects are similar to those of other medicines in the same class; they are mostly mild to moderate and temporary. Severe side effects may occur rarely with Privigen, including severe allergic reactions.

The European Medicines Agency therefore decided that Privigen's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Privigen have 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 on Privigen, including the package leaflet and assessment reports, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/privigen.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 06-2026.